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United States Patent [19]

Lesh et al.

[11] Patent Number: 6,152,144

[45] Date of Patent: Nov. 28, 2000

[54] METHOD AND DEVICE FOR LEFT ATRIAL APPENDAGE OCCLUSION → Closure of Pillay

[75] Inventors: **Michael D. Lesh**, Mill Valley; **Erik J. van der Burg**, Sunnyvale, both of Calif.

[73] Assignee: **Appriva Medical, Inc.**, Sunnyvale, Calif.

[21] Appl. No.: **09/187,200**

[22] Filed: **Nov. 6, 1998**

[51] **Int. Cl.**[7] **A61B 17/00**

[52] **U.S. Cl.** **128/898**; 606/200

[58] **Field of Search** 606/1, 151, 108, 606/191.2; 623/1, 11, 12; 128/898

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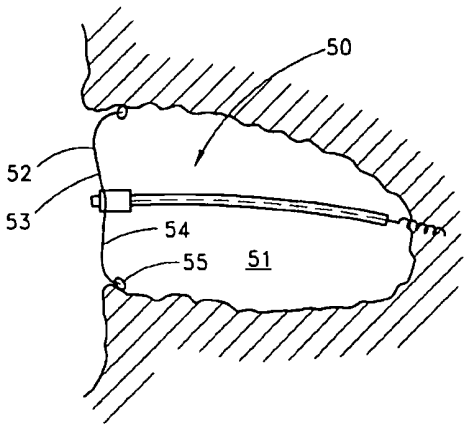
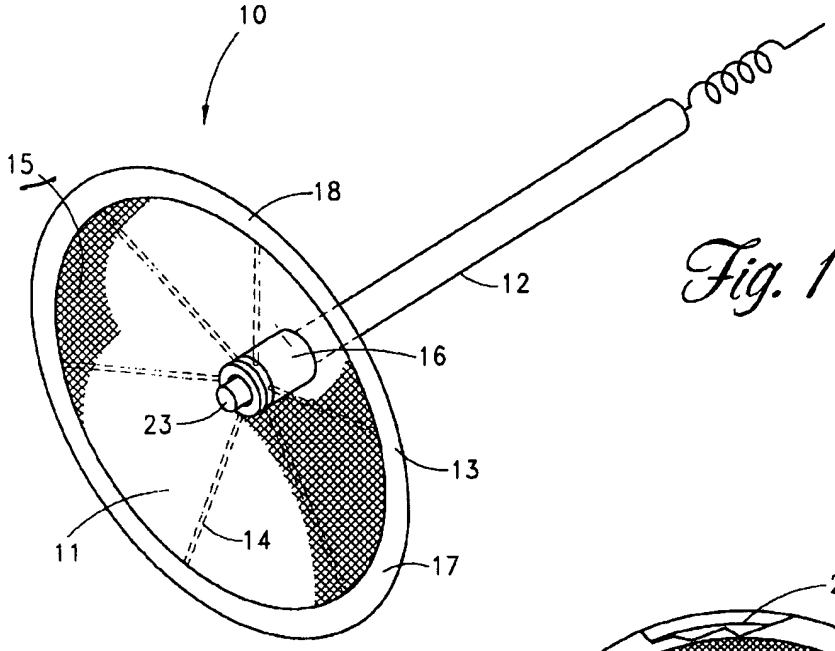
Attorney, Agent, or Firm—Knobbe, Martens, Olson & Bear, LLP

[57] **ABSTRACT**

A device and method for obliterating or occluding a body cavity or passageway, in particular, the left atrial appendage of a patient's heart. The procedure can be carried out intraoperatively, but is preferably carried out percutaneously by use of a delivery catheter to position an occluding device adjacent a patient's left atrial appendage. The occluding device may prevent the passage of embolic or other material to or from the left atrial appendage by volumetrically filling the appendage, closing the opening of the appendage with an occluding member, or pulling the tissue around the opening of the appendage together and fixing it in a closed state.

29 Claims, 13 Drawing Sheets





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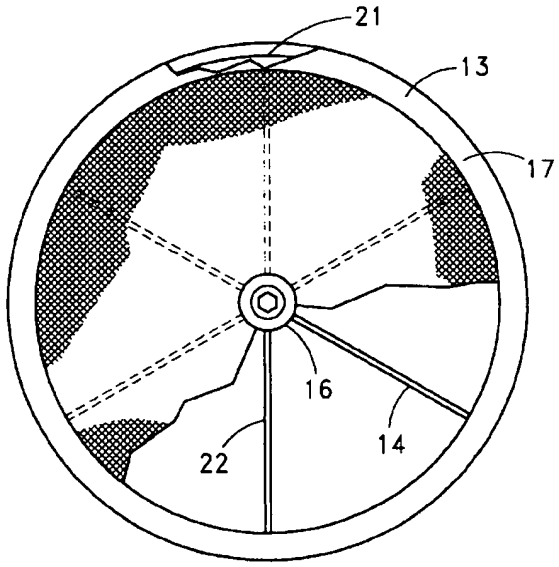
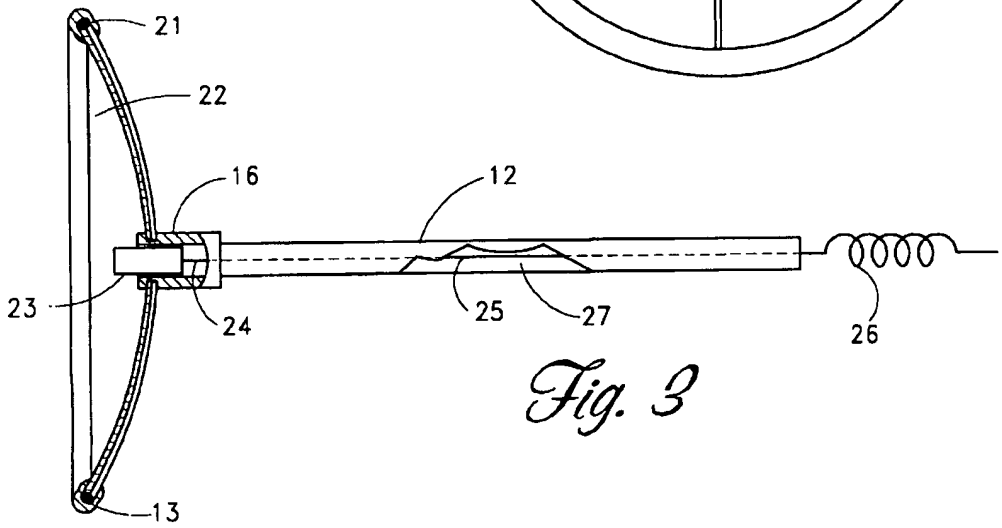


Fig. 2



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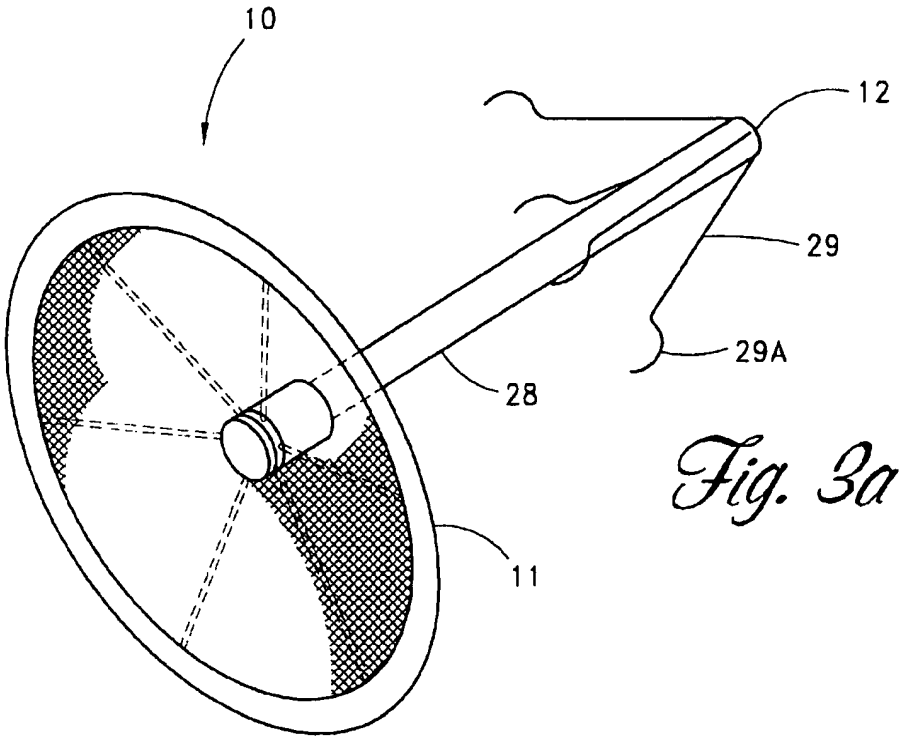

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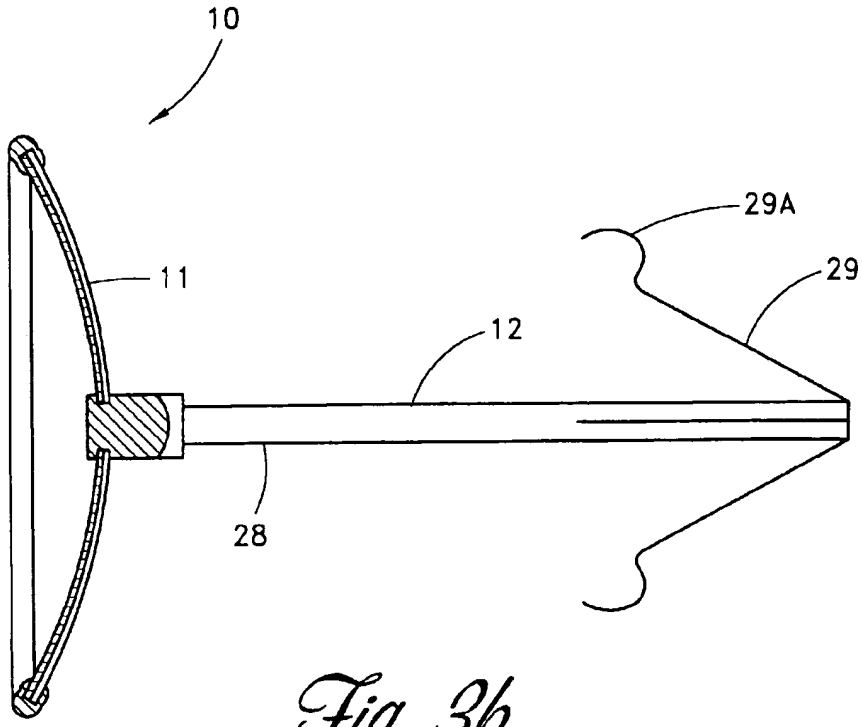

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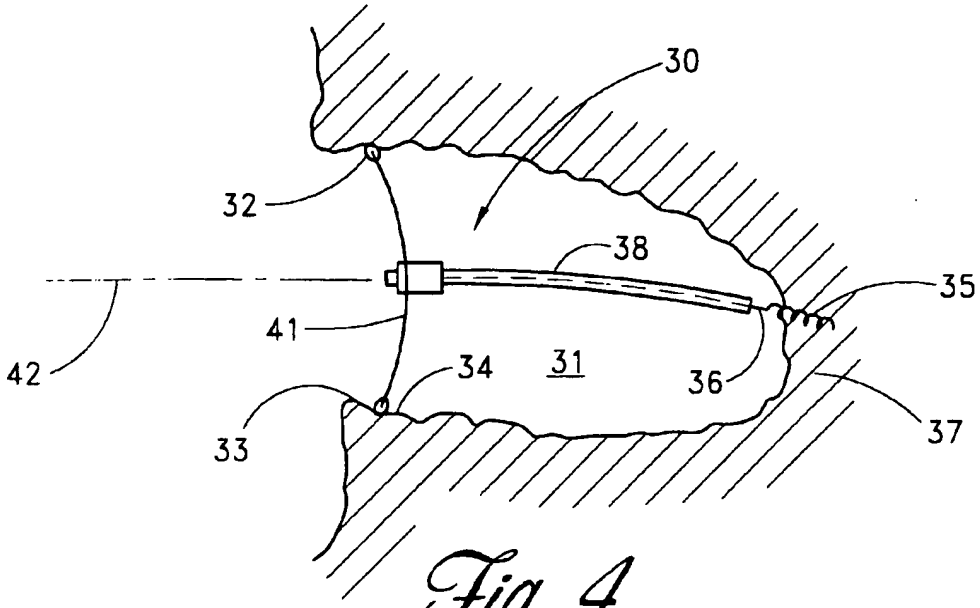
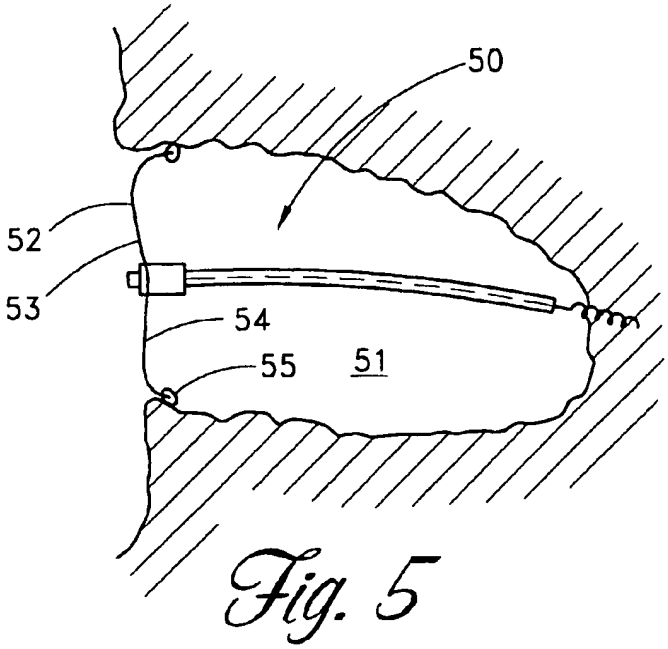


Fig. 4



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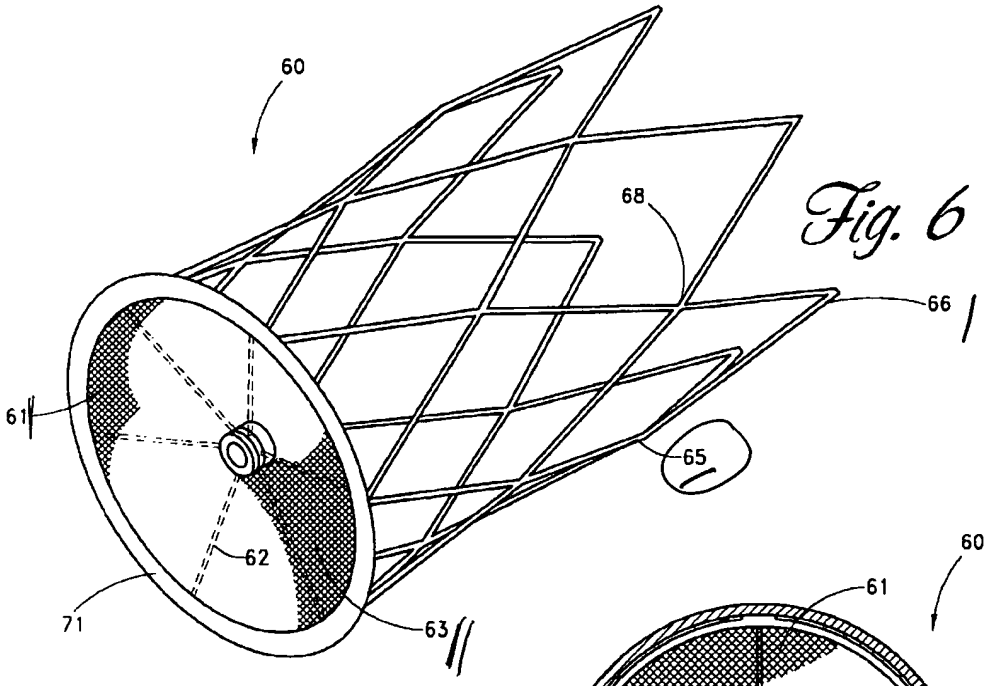

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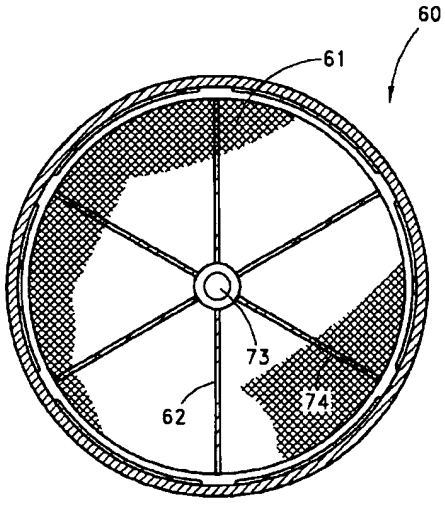

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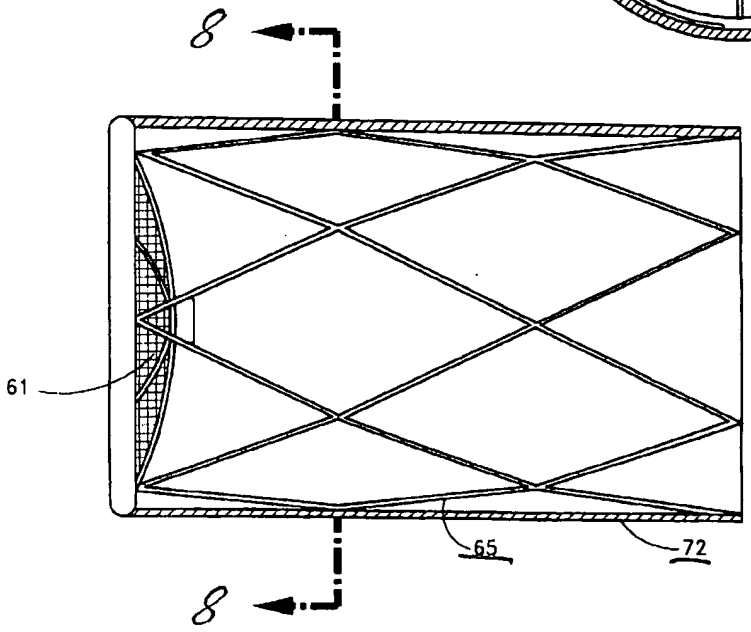

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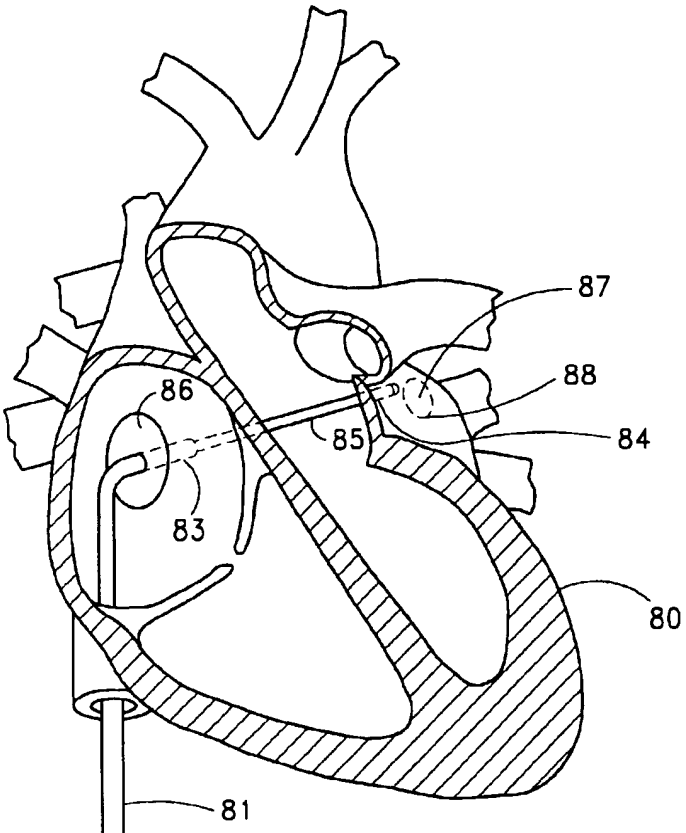

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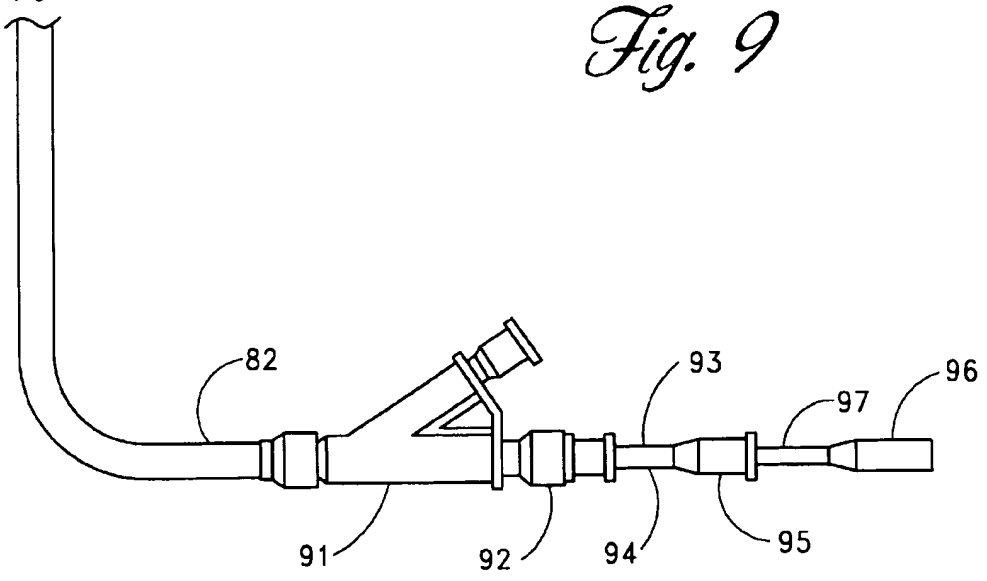

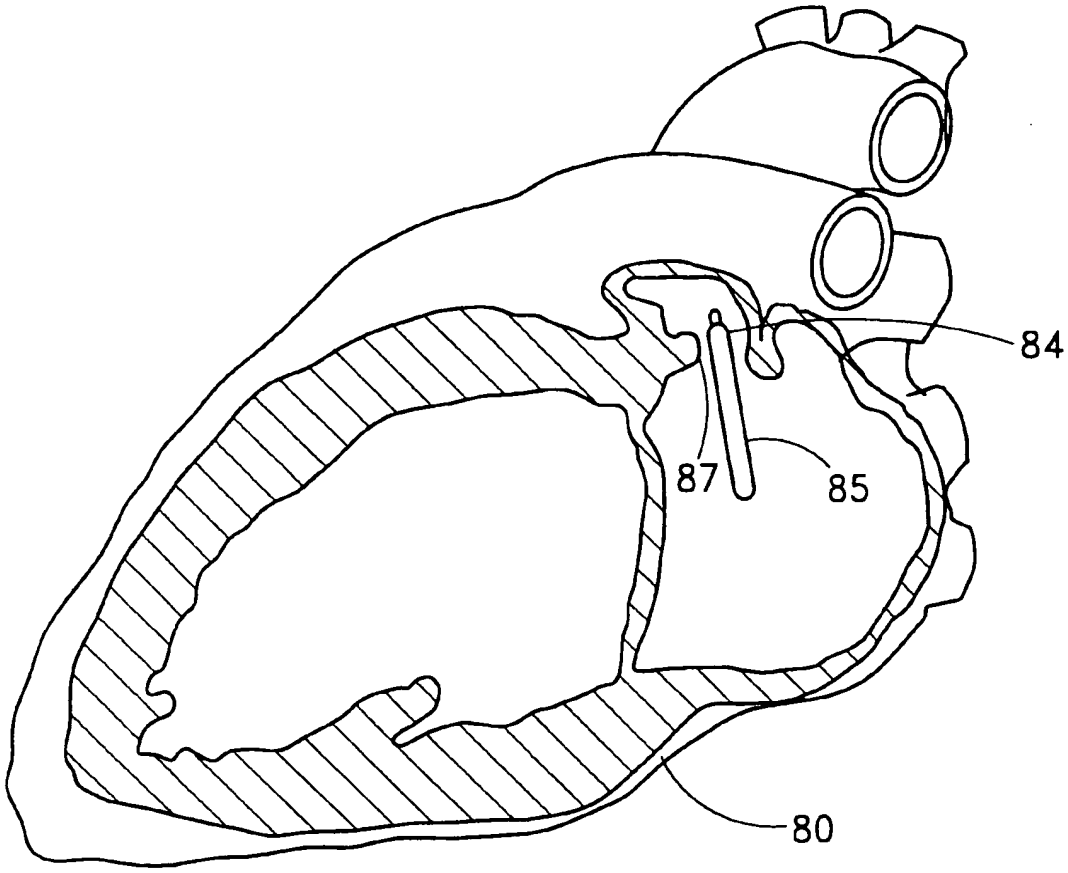

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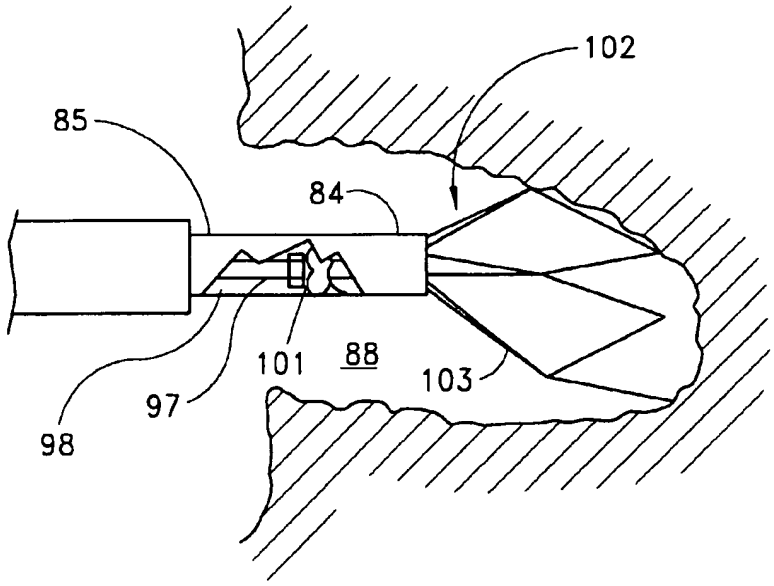

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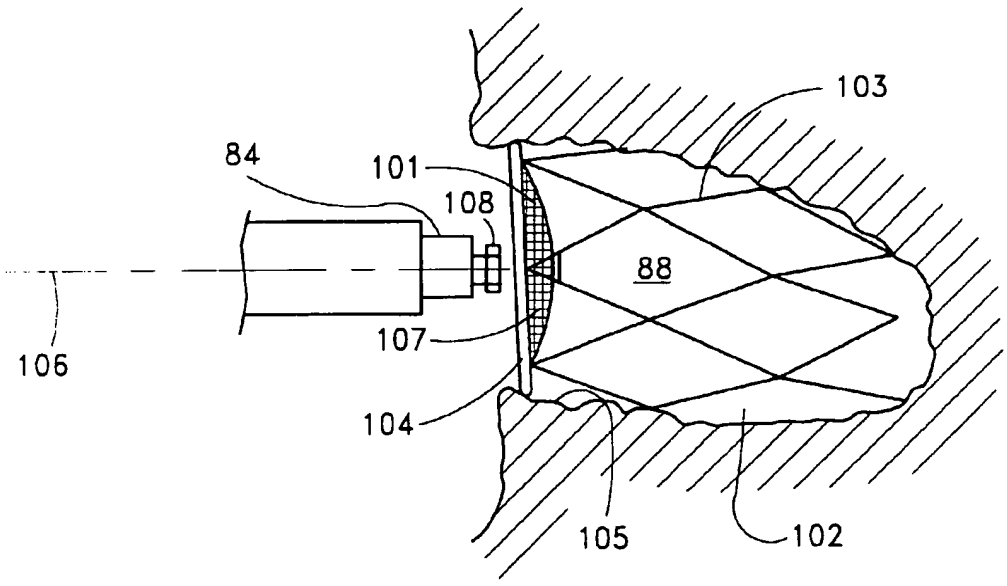

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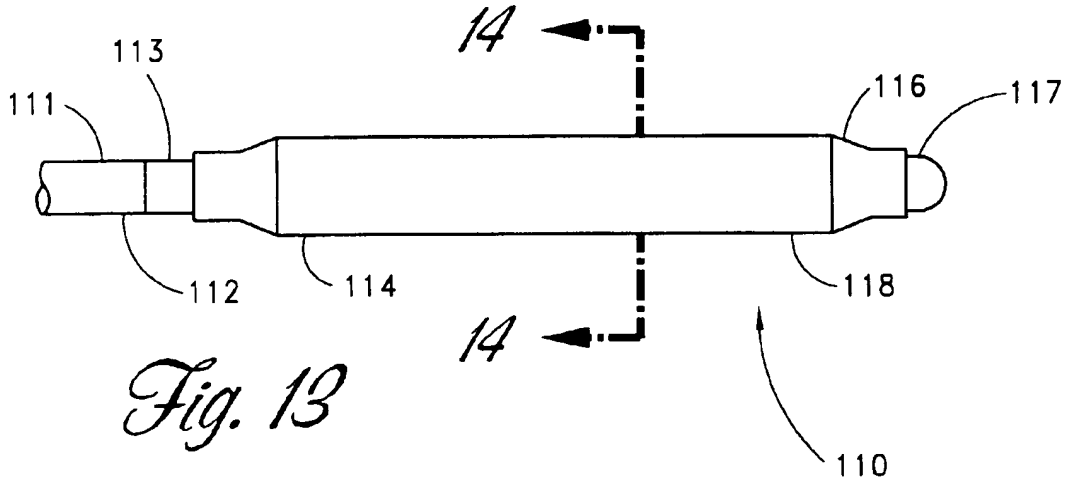
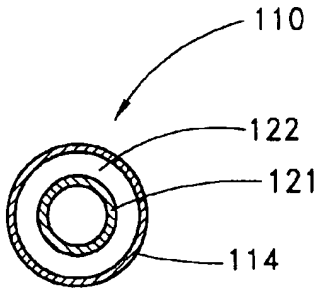


Fig. 13



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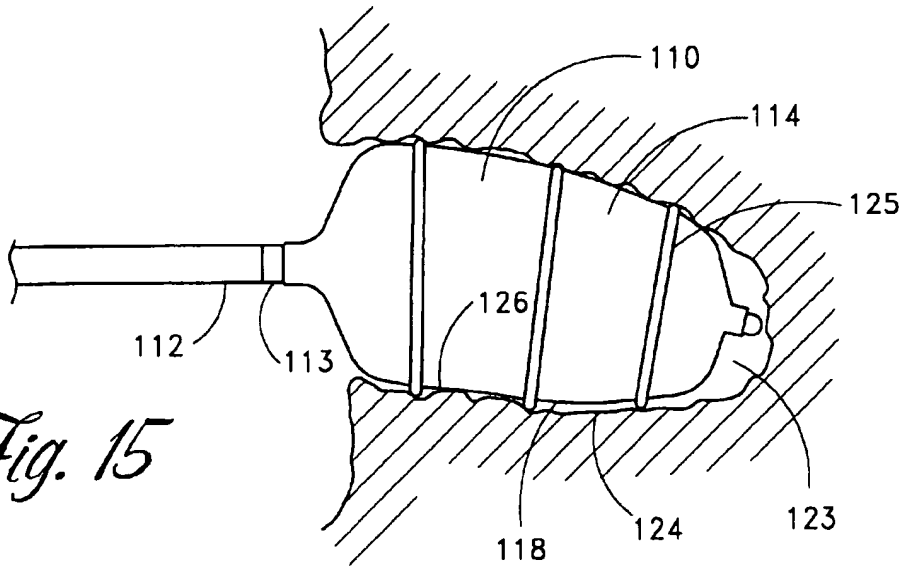
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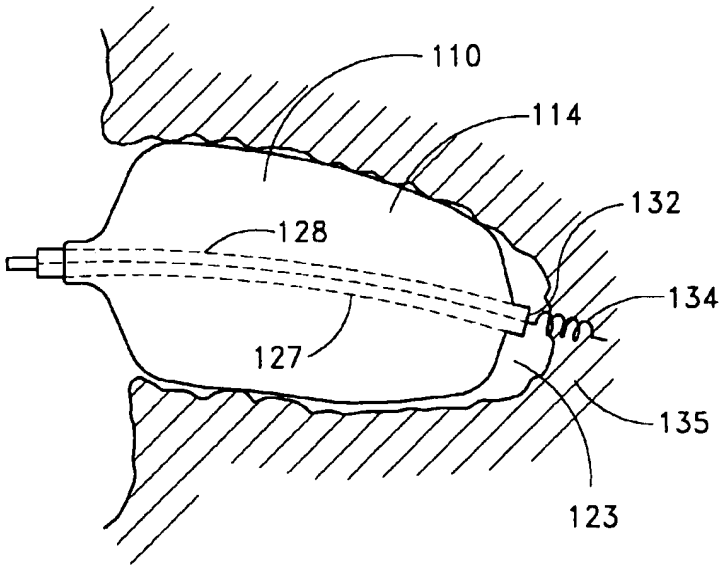
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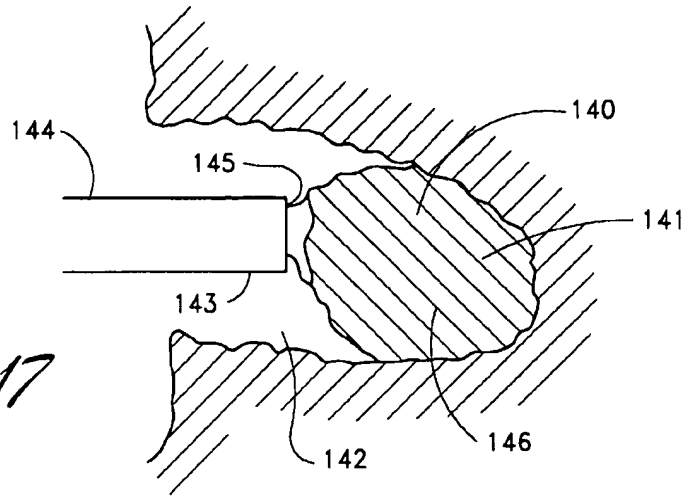

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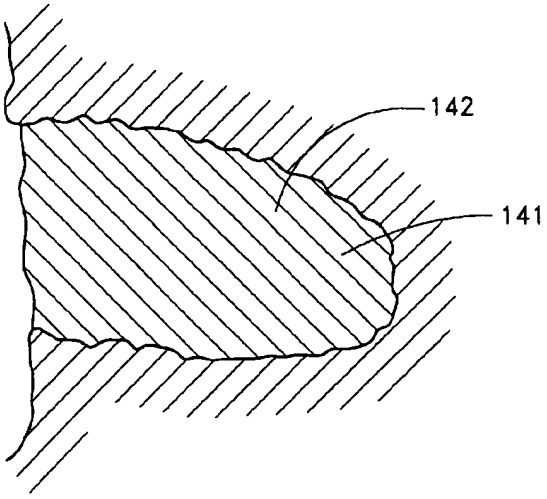

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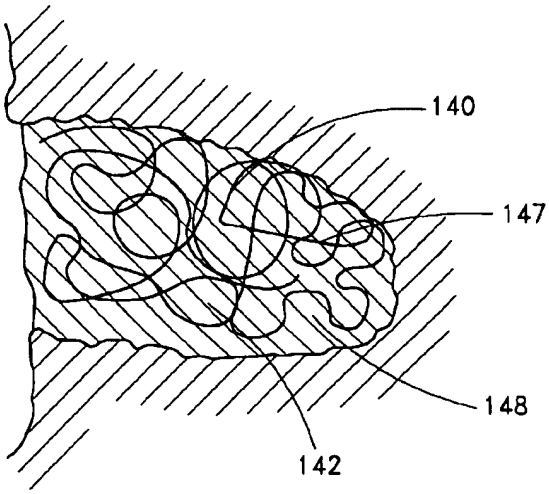

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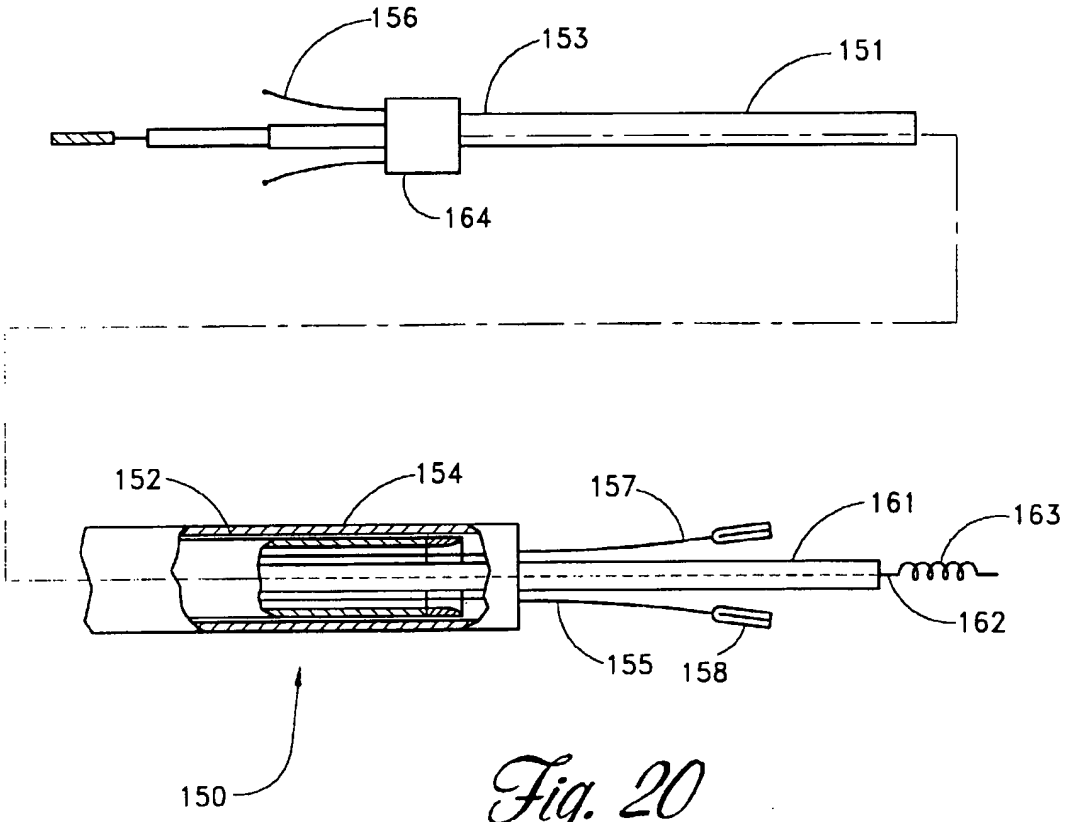

Fig. 20

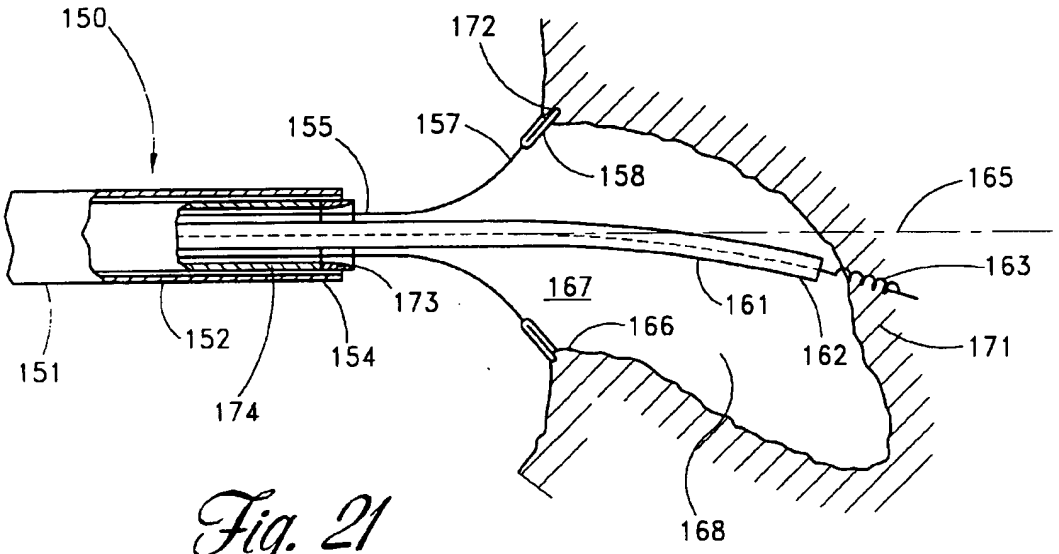
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Fig. 21

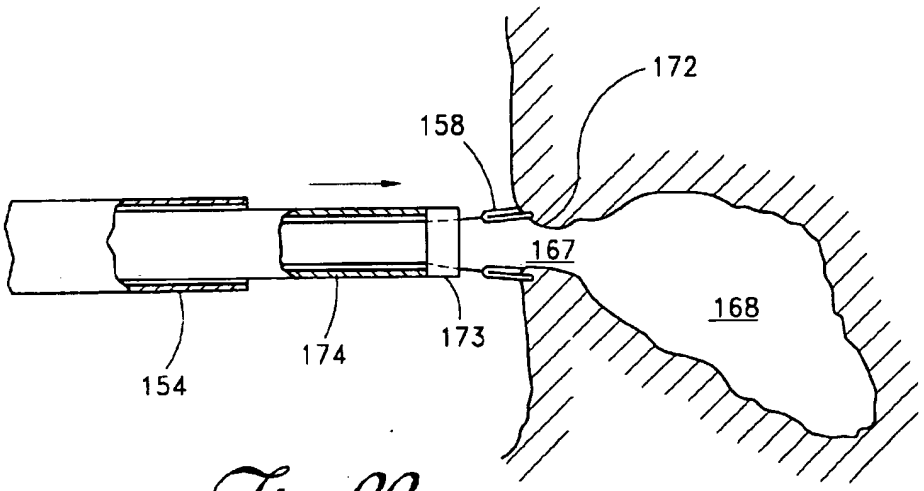
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Fig. 22

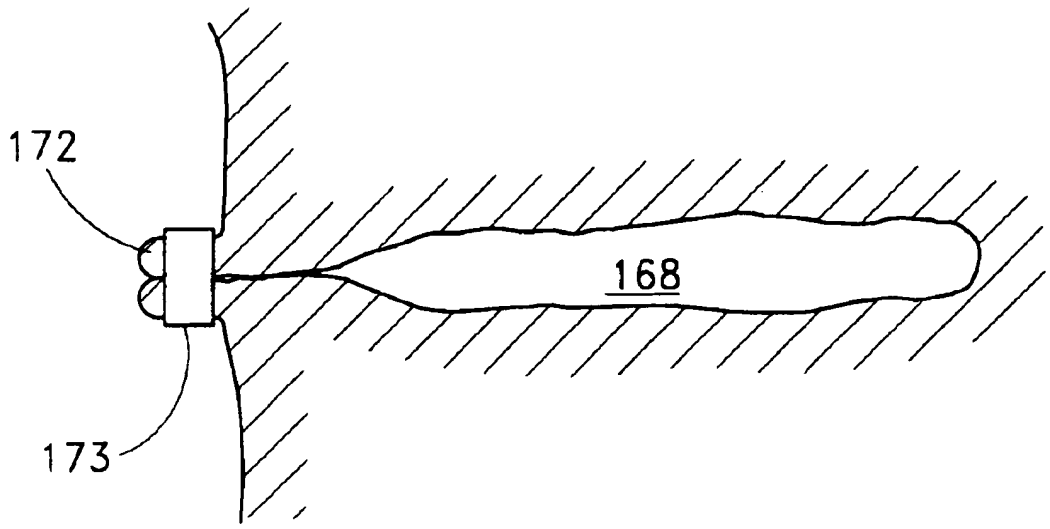

Fig. 23

METHOD AND DEVICE FOR LEFT ATRIAL APPENDAGE OCCLUSION

BACKGROUND

Embolic stroke is the nation's third leading killer for adults, and is a major cause of disability. There are over 80,000 strokes per year in the United States alone. The most common cause of embolic stroke emanating from the heart is thrombus formation due to atrial fibrillation. Atrial fibrillation is an arrhythmia of the heart that results in a rapid and chaotic heartbeat that produces lower cardiac output and irregular and turbulent blood flow in the vascular system. There are over five million people worldwide with atrial fibrillation, with about four hundred thousand new cases reported each year. Atrial fibrillation is associated with a 500 percent greater risk of stroke due to the condition. A patient with atrial fibrillation typically has a significantly decreased quality of life due, in large part, to the fear of a stroke, and the pharmaceutical regimen necessary to reduce that risk.

For patients who have atrial fibrillation and develop atrial thrombus therefrom, the clot normally occurs in the left atrial appendage (LAA) of the heart. The LAA is a cavity which looks like a small finger or windsock and which is connected to the lateral wall of the left atrium between the mitral valve and the root of the left pulmonary vein. The LAA normally contracts with the rest of the left atrium during a normal heart cycle, thus keeping blood from becoming stagnant therein, but often fails to contract with any vigor in patients experiencing atrial fibrillation due to the discoordinate electrical signals associated with AF. As a result, thrombus formation is predisposed to form in the stagnant blood within the LAA. Blackshear and Odell have reported that of the 1288 patients with non-rheumatic atrial fibrillation involved in their study, 221 (17%) had thrombus detected in the left atrium of the heart. Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. Ann Thorac. Surg., 1996.61(2):755–9. Of the patients with atrial thrombus, 201 (91%) had the atrial thrombus located within the left atrial appendage. The foregoing suggests that the elimination or containment of thrombus formed within the LAA of patients with atrial fibrillation would significantly reduce the incidence of stroke in those patients.

Pharmacological therapies for stroke prevention such as oral or systemic administration of warfarin or the like have been inadequate due to serious side effects of the medications and lack of patient compliance in taking the medication. Invasive surgical or thorascopic techniques have been used to obliterate the LAA, however, many patients are not suitable candidates for such surgical procedures due to a compromised condition or having previously undergone cardiac surgery. In addition, the perceived risks of even a thorascopic surgical procedure often outweigh the potential benefits. See Blackshear and Odell above. See also Lindsay BD. Obliteration of the left atrial appendage: A concept worth testing. Ann Thorac. Surg., 1996.61(2):515. What has been needed is a less invasive system and method for containment or elimination of thrombus formation in the LAA of patients with atrial fibrillation. The present invention satisfies these and other needs.

SUMMARY

The present invention is directed to a device and method for obliterating or occluding a body cavity or passageway. Specifically, the invention is directed to a device and method for obliterating or occluding the left atrial appendage of a patient's heart, preferably by percutaneous methods which obviate the need for invasive surgical procedures. One purpose of obliterating or occluding a body cavity or passageway, or particularly the left atrial appendage of a patient, is to prevent the passage or egress of embolic material into the bloodstream of a patient.

One embodiment of an apparatus having features of the invention has an occluding member having an outer rim or periphery disposed around the perimeter of the occluding member, with the outer rim configured to sealingly engage a surface of a body cavity. The apparatus also has an anchoring device or means which is secured to the occluding member. The anchoring device or means may include an adhesive between the outer periphery and an inside surface of a body cavity, a suture or sutures which are engaging the outer periphery of the occluding member and the inside surface of the body cavity, or the like. The anchoring device or means serve to secure the outer periphery to a surface of a body cavity or passageway so as to prevent the passage of embolic material or other materials therethrough.

In another embodiment, an apparatus having features of the invention may have an occluding member and a retention member secured to the occluding member. The retention member is configured to engage and attach to a surface of a body cavity and maintain a position of the occluding member to sealingly engage the inside surface of the body cavity and prevent the passage of embolic material or the like therethrough. In embodiments of the apparatus which are intended to occlude a patient's LAA, the occluding member will typically be a frame structure of a high strength material such as stainless steel, a shape memory or pseudoelastic alloy, such as NiTi alloy, or a suitable composite material. The frame structure has a barrier or mesh material disposed over it and preferably secured to it to act as a barrier to the passage of embolic material or fluids. The frame structure serves to support the barrier or mesh material in an outwardly expanded state to substantially occupy at least a portion of the cross section of a body cavity or passageway within which it is disposed. The mesh or barrier material can be any suitable material for preventing the passage of fluids, embolic material or other material suspended in fluids. Typical examples of suitable materials for the barrier include a Nylon or Dacron mesh. Preferably, the barrier or mesh material is made from PTFE or ePTFE having a pore size of up to about 0.04 inches, preferably up to about 0.005 inches. Other suitable materials may include polyurethanes, polyamides, polyethylenes or the like. The outer rim or periphery of the occluding member is preferably made of a soft polymer material which facilitates a seal between the outer rim and the inside surface of the body cavity. The outer rim may have a radial hoop of a metal or other high strength material or composite to provide outward radial pressure on the inside surface of the body cavity, and to maintain the shape of the outer rim. The occluding member may have a transverse dimension of about 0.5 to about 5 cm, preferably about 1 to about 2 cm.

The retention member secured to the occluding member may have any suitable configuration which maintains the position of the occluding member within the body cavity or passageway so as to form at least a substantial seal with the surface therein and prevent the passage of embolic material. Preferably, the retention member is an expandable member configured to engage the inside surface of the body cavity or passageway. The expandable member may be an expandable cylindrically shaped wire structure, typically with linked metallic elements which are capable of self expansion from a constrained state. The expansion member is preferably

made from a shape memory or pseudoelastic alloy such as NiTi, or the like, but may also be made from high strength materials such as stainless steel, MP35N and other suitable materials. The expandable member can be covered with a polymer fabric or mesh to act as a buffer between the metallic elements of the expandable member and the inside surface of the body cavity within which it is disposed. The outer sheath may be made of Dacron, Nylon, TFE, PTFE, ePTFE, polyurethane or the like.

In another embodiment of a device having features of the invention, the retention member may be a tissue penetrating shaft which is designed to penetrate an inner wall of a body cavity, preferably the fundus of a body cavity, and be mechanically secured thereto. In a particular embodiment of the tissue penetrating shaft, the distal extremity of the shaft has a helically shaped extension which screws into the tissue of the wall of a body cavity and is thereby mechanically secured thereto. The tissue penetrating shaft may have a length of about 0.5 to about 7 cm, preferably about 1 to about 4 cm, and more preferably about 1.5 to about 3 cm. An alternative embodiment of the tissue penetrating shaft would include radially extending members from the distal end of a shaft in place of or in conjunction with the helically shaped extension. The radially extending members serve to center the shaft within the body cavity or passageway, and also to engage the tissue of the body cavity or passageway to prevent axial movement of the shaft and occluding member. The shaft can have up to about 20 radially extending members, but preferably has about 3 to about 10 radially extending members.

Preferably a method of closing off or blocking a body cavity, in particular a patient's LAA, is performed in a non-invasive or percutaneous manner. Delivery of an occluding device is typically carried out via a Mullin's trans-septal approach whereby a trans-septal catheter and needle are delivered percutaneously from a point of insertion into the right femoral vein under local anesthesia. Single or biplanar flouroscopy can be used to image the trans-septal catheter during the procedure and guide the distal end of the catheter to the desired site. It is therefor advantageous for at least portions of the trans-septal catheter and LAA occlador device to be at least partially radiopaque. The trans-septal catheter is advanced through the right femoral vein into the right atrium and positioned adjacent the coronary septum. The needle is advanced from the distal end of the catheter and punctures the septum in a desired location. The trans-septal catheter is then advanced over the needle through the septum and into the left atrium. Preferably, the distal end of the trans-septal catheter or any other type of delivery catheter used for this procedure has a distal tip portion with angulation of up to about 40°, preferably about 10° to about 30° with respect to a longitudinal axis of the catheter disposed immediately proximal to the angled distal tip portion. An angled discharge axis of the distal end of the delivery catheter facilitates access to the opening of a patient's left atrial appendage. The needle assembly is then withdrawn leaving an open lumen within the trans-septal catheter with access to the left atrium. The LAA occluder device is then advanced from the proximal end of the trans-septal catheter to the distal end thereof and into or adjacent the patient's LAA. Once the occluder device is properly positioned, it can be deployed. Proper positioning of the occluder device can be determined by flouroscopy, intracavity or extracorporeal ultrasonic imaging, including transesopheogeal ultrasonic imaging (TE Echo), CT, MRI or any other suitable imaging technique.

Alternatively, the procedure to position and deploy the occluding member may be performed intraoperatively in a stand alone procedure or in conjunction with another procedure which provides access to the LAA or other desired passageway or cavity.

In another embodiment of an apparatus having features of the invention, a device for occluding a body cavity or passageway has an occlusive body configured to at least partially fill the volume of the left atrial appendage or other desired cavity or passageway of a patient. In one aspect of the invention, the occlusive body is an inflatable member which is detachably secured to a delivery catheter and configured to fit within, or preferably substantially fill the LAA of a patient. The inflatable member may also have a retention member secured to it which serves to engage the inner surface of a body cavity or passageway and maintain the position of the inflatable member relative to the body cavity or passageway. The inflatable member is configured to engage the inside surface of the LAA to prevent the passage of fluid or embolic material therefrom. Embolic material may be fluids, particulate suspended in fluids such as blood clots, gas bubbles, solid tissue or the like. In addition to or in lieu of the retention member, the inflatable member or balloon may have a ribbed surface which is shaped so as to engage the trebecula of the inside surface of a patient's LAA. The ribs should extend radially about 1 to about 4 mm from the nominal surface of the inflatable balloon, and should be spaced about 3 to about 8 mm from each other, and can be circumferential, longitudinal or spirally configured. The inflatable balloon may also include materials designed to induce fibrosis, such as Dacron®. Typically, the inflatable balloon is inflated within the LAA by injection of saline, silicone, or other suitable material.

In another aspect of the invention, the occlusive body may be a coiled member or members, in particular, one or more helical metallic coils having either a straight shape in a relaxed state or another configuration such as random, helical, convoluted shape in the relaxed state. When the coil is introduced into the cavity or passageway of the patient, it can assume the shape of a coiled mass that serves to occlude the cavity or passageway. The occlusion may result from the mechanical packing of the cavity or passageway, or may be augmented by thrombogenesis caused by the occlusive member. The coils may have a length of about 1 to about 20 cm and may have a diameter of about 0.01 to about 0.02 inches. The material from which the coils are wound can have a cross sectional dimension of about 0.001 to about 0.05 inches, preferably about 0.002 to about 0.006 inches. The occlusive coil can be made from any suitable material including stainless steel, NiTi alloy, or suitable radiopaque metals or composites such as gold, platinum, tantalum or iridium or alloys thereof. In an alternative embodiment, the occlusive coil is secured to a covering element or occluding member which is disposed in the ostium or opening of a body cavity to prevent the passage of embolic material therethrough.

In yet another aspect of the invention, the occlusive body may be a polymer mass or mass of other biocompatible material that can be introduced or injected into a body cavity or passageway, in particular, into the left atrial appendage of a patient. The polymer mass may be injected in a flowing fluid or gel form, and then harden to a non-flowing solidified or hardened mass with the passage of time or with elevated temperatures. Examples of suitable polymeric materials would include various epoxies, hydrogels, and adhesives, including polymers such as n butyl cyanoacrylate, polyisocyanate (polyurethane prepolymers), moisture curing silicone, synthetic polymers in non-aqueous but water miscible solvents (DMSO), latex, fibrin, and collagen type IV.

In general, the occlusive body would be deployed or delivered to the LAA percutaneously, as with the trans-septal approach discussed above. However, it may also be deployed intraoperatively during an invasive procedure, or ancillary to another procedure which gives access to the LAA. The occluding mass could also be secured to a covering element or barrier that is disposed within the ostium or opening of a body cavity to prevent the passage of occlusive or embolic material therethrough.

Another device having features of the invention is used to close a body cavity or LAA off permanently at its opening by pulling the opening closed and mechanically fixing the opening in a closed state. An apparatus for closing off a cavity or LAA of a patient having features of the invention generally has an elongate shaft with proximal and distal ends and a lumen within the shaft. Movably or slidably disposed within the lumen of the shaft are a plurality of tissue attachment members which also have proximal and distal ends. The tissue attachment can be accomplished by mechanical grasping or hooking, but can also be vacuum or suction actuated. The attachment by the tissue attachment members can be self activating or initiating upon contact with or penetration of tissue, or may be controlled from the proximal end of elongate members which are secured to the tissue attachment members and are also at least partially slidably disposed within the lumen of the elongate shaft. The elongate members may contain or house electrical conductors, fiber optic cables, or control lines operatively connected to the tissue attachment members to transmit the appropriate energy, signal or force to the tissue attachment members in order to initiate and maintain tissue attachment, or to collect and transmit an image of the site.

The tissue attachment members and distal ends of the elongate members attached thereto are configured to extend beyond the distal end of the elongate shaft which can be positioned adjacent to tissue to be closed off. In this way, the tissue attachment members can extend distally and at an angle to a longitudinal axis of the elongate shaft and make contact with tissue and attach thereto. The tissue attachment members may then be retracted into the distal end of the elongate shaft so as to pull the various portions of the tissue together and close the cavity or opening of the LAA. The device preferably includes a closure member which is generally configured as a retaining ring which is slidably disposed over the elongate members and configured to restrain tissue collected and pulled together by the tissue attachment members upon retraction. The closure member may also be a staple which secures the tissue of the opening. The tissue of the annular edge of the cavity which has been collected and pulled together by the tissue attachment members may also be fixed or secured in the closed state by suturing, bonding with a biocompatible polymer adhesive, stapling, tissue welding or the like. Tissue welding suitable for use with the invention may be carried out with laser energy applied to the closed tissue. Laser energy may be supplied by Nd:YAG or HO:YAG laser types. Various configurations of surgical staples could be used to fix or secure the closed tissue of the body cavity or LAA, including the type disclosed by U.S. Pat. No. 4,603,693 to Conta et al. which is incorporated by reference herein in its entirety and which discloses a device for deploying surgical staples.

The apparatus for closing a body cavity is generally delivered in a non-invasive, preferably percutaneous manner. An elongate delivery catheter having an inner lumen is percutaneously delivered such that a distal end of the delivery catheter is adjacent the opening of the patient's body cavity to be closed off. The closure device or apparatus for closing off a cavity or LAA of a patient is advanced distally within the delivery catheter from the proximal end thereof. The closure device is then advanced out of the distal end of the delivery catheter, and the tissue attachment members and elongate members advanced distally from the elongate shaft so that the tissue attachment members are in contact with the tissue of the opening of the body cavity to be closed. The tissue attachment members are then activated so as to attach to the tissue. The tissue attachment members are then retracted proximally back into the elongate shaft and the closure member advanced distally, preferably by distal movement of an elongate push shaft disposed proximal to the closure member and slidably disposed over the elongate members of the closure device. The closure member is advanced until it is disposed over the tissue of the cavity opening that is attached to the tissue attachment members and confines the tissue of the cavity opening so as to close off the cavity. The tissue attachment members can then be deactivated and withdrawn, and the closure device and delivery catheter withdrawn proximally to complete the procedure.

These and other advantages of the invention will become more apparent from the following detailed description when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a perspective view of an embodiment having features of the invention with an occluding member and a retention member.

FIG. **2** shows an end view of the apparatus of FIG. **1** in partial section.

FIG. **3** shows a longitudinal cross sectional view of the apparatus of FIGS. **1** and **2**.

FIG. **3A** shows a perspective view of an apparatus having features of the invention.

FIG. **3B** shows an elevational view in partial section of the apparatus of FIG. **3A**.

FIG. **4** shows an elevational view of an apparatus having features of the invention in a deployed state within a body cavity.

FIG. **5** shows an elevational view of an apparatus having features of the invention in a deployed state within a body cavity.

FIG. **6** shows a perspective view of an apparatus for sealing off a body cavity having features of the invention.

FIG. **7** shows an elevational view in partial section of an apparatus for sealing off a body cavity having features of the invention.

FIG. **8** shows a transverse cross-sectional view of the apparatus of FIG. **7** taken along lines **8—8**.

FIG. **9** shows a schematic view of a patient's heart with a trans-septal catheter deployed through the septum and a delivery catheter and apparatus for sealing off a body cavity disposed therein.

FIG. **10** shows a schematic view of a patient's heart in partial section with a delivery catheter disposed within the opening of the LAA.

FIG. **11** shows a magnified view of the delivery catheter distal end and the LAA of a patient of FIG. **10** with an apparatus for sealing off a body cavity partially deployed within the LAA.

FIG. **12** shows the apparatus for sealing off a body cavity of FIG. **11** fully deployed within a LAA.

FIG. 13 shows an elevational view of a device for occluding a body cavity having features of the invention.

FIG. 14 shows a transverse cross sectional view of the device for occluding a body cavity of FIG. 13 taken along lines 14—14.

FIG. 15 shows a device for occluding a body cavity having features of the invention deployed within a LAA.

FIG. 16 shows a device for occluding a body cavity having features of the invention deployed within a LAA.

FIG. 17 shows a LAA being occluded by a method having features of the invention.

FIG. 18 shows a LAA occluded by method having features of the invention.

FIG. 19 shows a LAA occluded by method having features of the invention.

FIG. 20 is an elevational view of an apparatus for closing an interior body cavity of a patient in partial section having features of the invention.

FIG. 21 is a schematic view of an apparatus for closing an interior body cavity of a patient in contact with tissue of a LAA.

FIG. 22 is a schematic view of an apparatus for closing an interior body cavity of a patient in contact with tissue of a LAA.

FIG. 23 shows a LAA which has been closed by a method having features of the invention.

DETAILED DESCRIPTION

FIGS. 1–3 show an embodiment of an occluding device **10** having features of the invention where an occluding member **11** is secured to a retention member **12** that is arranged to fix the occluding member in a desired position within a body passageway or cavity. The occluding member **11** generally has disc shape with an outer rim **13** around the perimeter of a frame structure **14** which supports a barrier **15**. The outer rim **13** can be circular or polygonal, or any other shape that is suitable for conforming to the inside surface of a body cavity. A hub **16** can be located near the center of the occluding member **11** which serves to connect the retention member **12** to the occluding member, in addition to other functions. The outer rim **13** is typically made from a soft polymer material **17** which permits flexibility of the outer rim and facilitates sealing of the outer rim against the inside surface of a body cavity or passageway. The barrier **15** can be a thin mesh or film of material which serves to block the passage of material within an area surrounded by the outer rim **13**. The barrier **15** can be secured to the outer rim **13** along its entire perimeter **18** in order to achieve a complete seal therebetween and can be molded into the outer rim **13** or bonded thereto by a suitable method such as gluing, welding, sewing or other suitable method. The outer rim **13** is at least partially supported by the frame structure **14** which connects the outer rim and the hub. The frame structure **14** can be made from one or more elements of high strength material such as stainless steel or MP35N, or may preferably be made from shape memory or pseudoelastic alloys such as NiTi. Preferably, the frame structure **14** is made from a material which can be self expanding from a constrained configuration so that the occluding device **10** can be delivered to the deployment site in a low profile an flexible configuration which facilitates percutaneous delivery. Preferably a radial hoop **21** is contained within the soft polymer material **17** of the outer rim **13** and serves to maintain the annular shape of the outer rim and facilitate radial expansion of the outer rim from a constrained position or configuration. The radial hoop **21** may be isolated within the soft polymer material **17** of the outer rim **13**, or may be connected to at least some the elements **22** of the frame structure **14**, in order to have stronger mechanical joint between the outer rim and the frame structure. The radial hoop **21** is shown in a substantially circular configuration, but may also be polygonal or otherwise suitably shared, and may have connections or joints spaced thereon to facilitate contraction or folding of the device for non-invasive delivery.

In addition to connecting the retention member **12** and the occluding member **11**, the hub **16** may serve to house a rotational coupling **23** which is connected to the proximal end **24** of a tissue penetrating shaft **25** within the retention member. The rotational coupling **23** allows the transfer of torque to the tissue penetrating shaft **25** which preferably has a helically shaped extension or distal extremity **26** which is configured to screw into tissue and be mechanically fixed thereto. Longitudinal movement of the tissue penetrating shaft **25** relative to the retention member **12** and hub **16** may be prevented by sizing a lumen **27** of the retention member which contains the tissue penetrating shaft such that the helically shaped extension **26** at the distal end is too large to pass through the lumen and the proximal end **24** of the tissue penetrating shaft is prevented from passing through the lumen by the rotational coupling attached thereto. The rotational coupling **23** may also be configured to be longitudinally captured by the hub **16** but still be rotatably disposed therein.

FIGS. 3A and 3B depict an alternative embodiment of an occluding device **10** having an occluding member **11** and a retention member **12**. The retention member **12** has a shaft **28** and radially extending members **29** extending radially from a proximal end of the shaft. The radially extending members **29** serve to anchor the shaft **28** and the occluding member **11** by engaging the tissue surrounding the occluding device. Preferably, the radially extending members are self expanding from a constricted state and are made of a pseudo elastic alloy such as NiTi, or a high strength material such as stainless steel. Although it is preferable for the radially extending members **29** to be self expanding from a constricted state, they may also be expanded by use of shape memory properties or a radial outward force as would be provided by an inflatable balloon or the like. The shaft **28** can be a single element or made of multiple elements, and can be made from the same materials as the radially extending members or different materials such as polymers or polymer composites. The radially extending members **29** have a proximally directed bias at their radial extremities **29A** so that the members readily fold down and move easily in a distal direction during insertion of the occluding device **10**, but spring outward and aggressively engage surrounding tissue upon movement in a proximal direction. This configuration of the radially extending members **29** allows easy insertion into a body cavity, but prevents egress of the device **10** in and outward or proximal direction.

FIG. 4 depicts an occluding device **30** similar to that depicted in FIGS. **1–3** deployed within the left atrial appendage **31** of a patient. An outer rim or periphery **32** of the occluding device **30** is disposed adjacent the opening **33** of the left atrial appendage **31** in a position which allows for a substantial seal of the outer rim against the inside surface **34** of the LAA. A helically shaped distal extremity **35** of a tissue penetrating shaft **36** has been screwed into the wall tissue of the LAA and is mechanically secured thereto. A retention member **38** maintains the position of an occluding member **41** in a substantially perpendicular orientation with respect to a longitudinal axis of the LAA **42**.

FIG. 5 depicts an occluding device similar to that depicted in FIGS. 1–4 deployed within a LAA 51 of a patient similar to what is shown in FIG. 4. The structure of an occluding member 52 of the embodiment as shown in FIG. 5 differs from that shown in FIG. 4 in that a barrier 53 and frame structure 54 of the embodiment of FIG. 5 protrudes proximally from a plane defined by an outer rim 55. This configuration may be useful for certain morphologies of patient's LAAs. One object of the invention is to create a smooth surface outside the body passageway or cavity in order to prevent turbulent flow or eddies of blood or other bodily fluid within the cavity or passageway. The alternative configuration of the occluding device 50 shown in FIG. 5 may be useful in this regard.

FIG. 6 shows an alternative embodiment of an occluding device 60 which has an occluding member 61, a frame structure 62, a barrier 63 and a retention member in the form of an expandable member 65 which has linked elements 66 that are preferably expandable from a constrained configuration. The expandable member 65 is generally cylindrical in shape and can have a series of circumferential linked elements 66 connected by links 68. Although FIG. 6 depicts the expandable member 65 as a series of linked elements 66, those skilled in the art will realize that a similar effect can be achieved with a single wire in a helical configuration or a plurality of wires in a mesh or braided configuration, or any other suitable configuration that can be self expanding from a constrained configuration or expanding with the application of heat or other form of energy or force. For example, the expandable member 65 may be configured to be deployed by an outward radial force delivered from within the expandable member. An inflatable balloon or the like could be used to exert such a force. The expandable member is preferably secured to an outer rim 71 of the occluding member 61 but may also be secured to the frame structure 62 directly or indirectly. The expandable member 65 can be self expanding from a constrained configuration as can the occluding member 61 and the frame structure 62 and outer rim 71 thereof. The frame structure 62, outer rim 71 and barrier 63 may have construction similar to that described above with regard to the similar elements of the embodiments depicted in FIGS. 1–5.

Referring to FIG. 7, the expandable member 65 as shown in FIG. 6 may also have a sheath 72 disposed around it so as to act as a shield between the expandable member and an inner surface of a patient's body cavity or passageway. The sheath 72 may facilitate the sealing function of the occluding member 61, but is primarily intended to prevent damage to either tissue on the inside surface of a body cavity or to the linked elements 66 of the expandable member. The sheath 72 may surround all or part of the expandable member 65 and may be made from a variety of suitable biocompatible materials such as Dacron®, Nylon, TFE, PTFE or ePTFE. The sheath 72 may be a weave, braid, film or have any other suitable configuration. Expandable member 65 may also be coated by dipping, spraying, or other suitable process with a friction reducing material such as Teflon®, or with an active compound such as heparin.

FIG. 8 shows a transverse cross sectional view of the embodiment of FIG. 7 taken at lines 8—8. The frame structure 62 has an axis or hub 73 disposed at approximately the center of the frame structure which serves to connect the various radial elements 74 of the frame structure. The hub 73 can have an independent structure that links the several elements 74 of the frame structure 62 or it may be merely the terminus of the various frame structure elements and have a solid composition. In either structure, the hub 73 preferably allows a constrained configuration of the occluding member 61 to facilitate percutaneous delivery of the occluding device 60. The hub 73 may also have a lumen disposed therein to allow passage of a guidewire of other guiding member. Preferably, the lumen would have a self sealing valve or gasket which prevents the passage of fluid or embolic material once the guidewire or guiding member is removed from the lumen.

Referring to FIG. 9, a schematic view of a patient's heart 80 in partial section shows a trans-septal catheter 81 having a proximal end 82 and a distal end 83. The distal end 83 of the trans-septal catheter 81 is disposed within a patient's heart 80 with the distal end 84 of a delivery catheter 85 extending from the distal end 83 of the trans-septal catheter. The distal end 83 of the trans-septal catheter 81 has breached the septum 86 of the patient's heart 80 and is disposed adjacent the opening of the patient's LAA 88. At the proximal end 82 of the trans-septal catheter 81 there is a Luer connector 91 coupled to a hemostasis valve 92 which prevents the egress of blood from a lumen 93 of the trans-septal catheter 81. The proximal end 94 of the delivery catheter 85 extends proximally from the hemostasis valve 92 and has a Luer connector 95 attached to the proximal extremity thereof. The proximal end 96 of a plunger 97 extends from the Luer connector 95 of the delivery catheter. The proximal end 94 of the delivery catheter is arranged to allow rotational and axial movement of the plunger 97 while preventing blood or other bodily fluids from leaking between the delivery catheter 85 and the plunger 97.

Referring to FIG. 10, a patient's heart 80 is shown in partial section with the distal end 84 of a delivery catheter 85 disposed within the LAA opening 87. FIG. 11 is a magnified view of the LAA 88 shown in FIG. 10 and the distal end of the delivery catheter 84, which is shown in partial section, contains a plunger 97 which is slidably disposed within an inner lumen 98 of the delivery catheter 85 and serves to apply axial force in a distal direction on the collapsed occluding member 101 disposed within the delivery catheter so as to force the occluding device 102 from the delivery catheter and deploy it. An occluding device 102 having an expandable member 103 and an occluding member 101 secured thereto is partially deployed and extending from the distal end of the delivery catheter 84 into the patient's LAA 88. The occluding device 102 can also be guided into the patient's LAA 88 by use of an appropriate guidewire or guiding member.

FIG. 12 shows the occluding device 102 of FIG. 11 in a deployed state within the patient's LAA 88. An outer rim 104 of the occluding member 101 is in substantial sealing contact with the inside surface 105 of the LAA 88. The expandable member 103 has expanded so as to contact the inside surface 105 of the LAA and secure the occluding device 102 thereto and maintain the occluding member 101 in a substantially perpendicular orientation relative to a longitudinal axis 106 of the LAA 88. A barrier 107 is disposed within an area bounded by the outer rim 104 and is positioned to prevent the passage of embolic or other material to or from the LAA 88. The distal end 108 of the plunger 97 is extending from the distal end of the delivery catheter 84 after having pushed the occluding device 102 from the delivery catheter.

Referring to FIG. 13, an occluding device 110 having features of the invention is shown. The occluding device 110 has a delivery catheter 111 with a distal end 112, a detachment mechanism 113 disposed on the distal end of the delivery catheter and an occlusive body or inflatable member 114 detachably secured to the detachment mechanism.

The inflatable member **114** has a proximal end **115** and a distal end **116** with the proximal end being attached to the detachment mechanism **113** and the distal end terminating at an end cap **117**. The inflatable member **114** has an outside surface **118** that may contain a fibrosis inducing material such as Dacron® or other similar materials. The inflatable member **114** may be made from a fluid tight film of polymer material which can be either compliant or non-compliant. Preferably the inflatable member **114** is made from silicone, however, any suitable material such as polyethylene, polyurethane or PET can be used.

The detachment mechanism **113** can be activated by mechanical force or by delivery of thermal or optical energy by a suitable conduit. Alternatively, the inflatable member can be pushed into the LAA from the delivery catheter **111** by an elongate push member without the use of a detachment mechanism. The inflatable member **114** can be filled with a gas, fluid or gel which is injected under pressure through the delivery catheter **114** and into the inflatable member. Suitable fluids to inject would include saline and silicone. The inflatable member **114** may also be filled with a polymer material that can be hardened. A fluid, gel or polymer used to fill the inflatable member may contain contrast agents such as gold, tantalum, bismuth, barium sulfate or the like in order to improve visualization under flouroscopy or x-ray imaging.

FIG. **14** is a transverse cross sectional view of the occluding device **110** of FIG. **13** taken along lines **14—14**. An optional inner shaft **121** is shown disposed within the inflatable member **114**, preferably in a concentric arrangement. The inner shaft **121** provides longitudinal axial support to the inflatable member **114** so as to maintain a longitudinal dimension of the inflatable member **114** when it is being inflated and deployed. The inner shaft **121** may be solid or contain one or more lumens that may or may not be in fluid communication with an inner lumen **122** of the inflatable member **114**, and can be used for the passage of a guidewire or guiding member.

FIG. **15** depicts an alternative embodiment of an occluding device **110** which consists of an inflatable member **114** similar to the inflatable member of FIG. **13**, shown substantially deployed, within a patient's LAA **123**. The inflatable member **114** has been at least partially filled with a fluid, gas or gel within the patient's LAA **123** such that the outside surface of the inflatable member **118** is in contact with at least part of the inside surface **124** of the LAA. The inflatable member **114** can have rib members **125** which can mechanically interlock with the trebeculae **126** of the inside surface of the LAA **124** or other surface irregularities of the inside surface of a patient's body cavity or passageway. The rib members **125** form a complete circumference of the inflatable member **114**, but could also form a partial circumference, spiral configuration, or consist of random projections on the surface of the inflatable member **118**. The rib members **125** should extend radially about 1 to about 4 mm from the nominal surface of the inflatable member **114**, and are preferably spaced about 3 to about 8 mm from each other. The rib members **125** may be made from any suitable polymer material, but are preferably made from the same material as the inflatable member, and are integrally molded thereon, or bonded thereto with a heat weld or adhesive bond suitable for bonding flexibly medical polymers. The inflatable member **114** is depicted with the distal end of the delivery catheter **112** and detachment mechanism **113** attached. As an alternative, or in addition to the polymer rib members **125** shown in FIG. **15**, barbs or hooks could be secured to the outside surface of the inflatable member **114** which are configured to engage the inside surface of a patient's LAA **124**. Preferably, barbs or hooks disposed on the outside surface of the inflatable member and configured to engage the tissue of the inside surface of a patient's LAA **124** would have a proximally directed bias at their radial extremity so that the barbs would fold down and move easily in a distal direction during insertion of the inflatable member **114**, but would spring outward and aggressively engage the tissue of the body cavity upon movement in a proximal direction of the inflatable member.

FIG. **16** depicts an occluding device **110** consisting of an inflatable member **114** which is shown deployed within a patient's LAA **123**. The embodiment of the inflatable member **114** shown in FIG. **16** has an optional retention member **127** with a tissue penetrating shaft **128** which has a proximal **131** end and a distal end **132**. A rotational coupling **133** is disposed at the proximal end **131** of the tissue penetrating shaft **128** and a helically shaped extremity **134** is disposed at the distal end of the shaft **132**. The helically shaped distal extremity **134** is shown deployed within and mechanically engaging wall tissue **135** of the LAA so as to secure the inflatable member **114** and maintain its position within the LAA **123** of the patient.

FIG. **17** shows an alternative embodiment of an occlusive member **140** consisting of a polymer mass **141** which has been injected or delivered into a patient's LAA **142**. The distal end **143** of a delivery catheter **144** has a lumen **145** therein which extends to a proximal end of the delivery catheter which is in fluid communication with a source of pressurized polymer material. A source of pressurized polymer material **146** can be any type of pump or device capable of forcing a polymer fluid or gel into the proximal end of the delivery catheter with sufficient pressure to force the polymer fluid or gel out the distal end **143** of the delivery catheter **144** and into a patient's body cavity or passageway. The delivery catheter **144** may be positioned by the techniques discussed above, e.g. the Mullins trans-septal approach or any other suitable method. Once the distal end of the delivery catheter **143** is disposed within a desired portion of the patient's LAA **142**, the polymer mass **141** may be injected to fill the cavity to the desired level. The LAA **142** can be completely or partially filled with the polymer mass **141** which can be formulated to harden over time, with heat or remain in a fluid or gel state. The distal end of the delivery catheter can optionally include an expandable member which is used to substantially seal the delivery catheter against the inside surface of the opening of the patient's body cavity during the delivery of polymer material. The expandable member can be an inflatable balloon or the like which are well known in the art.

Optionally, a retention member **127** having a tissue penetrating shaft **128** or the like, such as shown in FIG. **16** with regard to the inflatable member **114**, may be deployed within the LAA **142** prior to injection of the polymer mass **141** and captured thereby so as to secure the polymer mass within the LAA. Alternatively, the polymer mass can be used to fill the patient's LAA and surround and secure a deployed device as shown in FIGS. **4** or **5** in the patient's LAA **142**.

Once a desired amount of polymer mass **141** has been injected into the LAA **142**, as assessed for example by TE Echo imaging, the delivery catheter **144** may be withdrawn and the procedure terminated. Preferably the entire LAA **142** of a patient is filled with the polymer mass **141** as shown in FIG. **18** and hardens or gels to maintain its shape. It may be desirable to have the polymer mass **141** retain a soft compressible form after setting or hardening so that it is at least partially compliant with the constrictive pumping action of

a heart and resistant to fatigue as a result thereof. A material used to form the polymer mass **141** may contain contrast agents such as gold, platinum, tantalum, bismuth or the like in order to better visualize the deployment of the polymer mass under fluoroscopic or x-ray imaging.

Another alternative embodiment of an occlusive member **140** can be found in FIG. **19** which shows an occlusive coil **147** which has been deployed within an LAA **142**. The occlusive coil **147** as shown has assumed a random configuration that is mechanically occluding the LAA **142** and which has induced clot and or fibrosis formation **148** which further facilitates occlusion of the LAA **142**.

An apparatus for closing off a body cavity or passageway **150** is shown in FIG. **20** which has features of the present invention. The apparatus **150** has an elongate shaft **151** with an inner lumen **152** and a proximal end **153** and a distal end **154**. Slidably disposed within the inner lumen **152** of the elongate shaft **151** are at least two elongate members **155** which have proximal ends **156** and distal ends **157** and have tissue attachment members **158** disposed on the distal ends. An optional distal anchor member **161** is also slidably disposed within the inner lumen **152** of the elongate shaft **151** and preferably has a distal end **162** terminating with a helical member **163**. The proximal end **153** of the elongate shaft **151** has a proximal control module **164** which seals the inner lumen **152** of the elongate shaft **151** and allows rotation and translation of the proximal ends **156** of the elongate members **155** and the distal anchor member **161** while maintaining a seal between said members to prevent leakage of bodily fluids therefrom. The proximal control module **164** can optionally be configured to control advancement and retraction of the elongate members **155** and control activation of the tissue attachment members **158**.

FIG. **21** shows the apparatus for closing off a body cavity **150** of FIG. **20** with the distal ends of the elongate members **157** and the tissue attachment members **158** extending distally from the distal end of the elongate shaft **154**. The distal ends of the elongate members **157** are angled or deflected from a longitudinal axis **165** of the elongate shaft **151** so as to engage tissue **166** of the opening **167** of the LAA **168** as shown. The elongate members **155** may be deflected by an abutment or angulation contained in the distal end of the elongate shaft **154**, but are preferably preshaped in an angled configuration which manifests when the distal ends are freed of the constraint of the inner lumen **152** of the elongate shaft an allowed to assume their relaxed preshaped condition. The helical member **163** at the distal end **162** of the distal anchor member **161** is engaged with the wall tissue **171** of the LAA **168** so as to provide an optional anchor that can be used to move the elongate shaft **151** relative to the distal anchor member **161** and give greater control of the longitudinal axial movement of the elongate shaft relative to the LAA opening **167**. The tissue attachment members **158** are shown attached to the annular edge **172** of the LAA opening **167**. Once the tissue attachment members **158** are attached, a closure member or retaining ring **173** may be advanced distally by applying axial force on an elongate push shaft **174** which draws the tissue attachment members **158** and the tissue attached thereto closer together as shown in FIG. **22**. As the closure member **173** is further advanced distally, the annular edge of the LAA **172** is drawn closed, and eventually, the annular edge of the LAA will be completely closed into a closed state with the closure member **173** surrounding and compressing the tissue of the annular edge as shown in FIG. **23**. Once a closed state of the LAA is achieved, the tissue attachment members **158** may be detached, and the apparatus for closing off a body cavity **150** withdrawn. One alternative method can have the tissue attachment members **158** drawn together by retracting them proximally into the distal end **154** of the elongate shaft **151** as opposed to distally advancing the closure member **173** with the elongate push shaft **174**. In this way, the annular edge of the LAA **172** can be drawn into a closed state within the distal end **154** of the elongate shaft **151** at which point the annular edge may be fixed in the closed state by a variety of methods including suturing, tissue welding, the application of a suitable biocompatible adhesive, surgical staples or the like.

While particular forms of the invention have been described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. A method of occluding a left atrial appendage of a patient comprising:

a) providing a device for occluding a body cavity comprising:
an occluding member, and
a retention member secured to the occluding member;

b) providing a delivery catheter having a proximal end and a distal end;

c) advancing the delivery catheter percutaneously through the patient's vasculature to a chamber within the patient's left atrium;

d) advancing the distal end of the delivery catheter and the device for occluding a body cavity adjacent the left atrial appendage; and

e) deploying the device for occluding a body cavity such that the occluding member substantially obstructs the passage of embolic material to and from the left atrial appendage.

2. The method of claim **1** wherein thrombotic or fibrotic material is removed from the patient's left atrial appendage prior to deployment of the device for occluding a body cavity.

3. The method of claim **2** wherein the thrombotic or fibrotic material is removed from the patient's left atrial appendage by aspiration through an aspiration lumen of a catheter having a port in the distal end thereof in fluid communication with the aspiration lumen which is operatively connected at its proximal end to a vacuum source.

4. The method of claim **1** wherein the retention member comprises an expandable member configured to engage an inside surface of the left atrial appendage and the device for occluding a body cavity is at least partially deployed by expanding the expandable member within the left atrial appendage so as to engage at least a portion of an inner surface of the left atrial appendage.

5. The method of claim **1** wherein the retention member comprises a tissue penetrating shaft configured to penetrate and be secured to tissue of the left atrial appendage and the device for occluding a body cavity is at least partially deployed by penetrating the tissue of the left atrial appendage with the tissue penetrating shaft such that the tissue penetrating shaft is mechanically secured thereto.

6. The method of claim **1**, wherein the retention member comprises a shaft having at least one radially extending member extending radially therefrom and configured to engage an inside surface of a patient's left atrial appendage and the device for occluding a body cavity is at least partially deployed by expanding the at least one radially expanding member from a constrained configuration so as to engage the tissue of the left atrial appendage.

7. The method of claim 6 wherein the at least one radially expanding member is comprised of a pseudoelastic alloy which is self expanding from a constrained configuration.

8. A method of occluding a left atrial appendage as in claim 1, wherein the occluding member comprises a self expandable frame.

9. A method of occluding a left atrial appendage as in claim 8, further comprising a barrier on the frame.

10. A method of occluding a left atrial appendage as in claim 9, wherein the barrier has a pore size of up to about 0.04 inches.

11. A method of occluding a left atrial appendage as in claim 9, wherein the barrier comprises a polymer selected from the group consisting of Dacron, Nylon, TFE, PTFE, ePTFE, and polyurethane.

12. A method of occluding a left atrial appendage as in claim 1, wherein the retention member comprises a self expandable wire structure.

13. A method of occluding a left atrial appendage as in claim 12, further comprising a polymer on the wire structure.

14. A method of occluding a left atrial appendage as in claim 1, wherein the first advancing step comprises advancing the delivery catheter through the right femoral vein.

15. A method of occluding a left atrial appendage of a patient, comprising the steps of:

providing a delivery catheter having a proximal end and a distal end, and a device for occluding a body cavity thereon, the device comprising an occluding member and a retention member secured to the occluding member;

advancing the delivery catheter into a chamber within the patient's left atrium;

positioning the device for occluding a body cavity adjacent the left atrial appendage; and

deploying the device for occluding a body cavity such that the occluding member substantially obstructs the passage of embolic material to and from the left atrial appendage.

16. The method of claim 15, wherein thrombotic or fibrotic material is removed from the patient's left atrial appendage prior to deployment of the device for occluding a body cavity.

17. The method of claim 16, wherein the thrombotic or fibrotic material is removed from the patient's left atrial appendage by aspiration through an aspiration lumen of a catheter having a port in the distal end thereof in fluid communication with the aspiration lumen which is operatively connected at its proximal end to a vacuum source.

18. The method of claim 15, wherein the retention member comprises an expandable member configured to engage an inside surface of the left atrial appendage and the device for occluding a body cavity is at least partially deployed by expanding the expandable member within the left atrial appendage so as to engage at least a portion of an inner surface of the left atrial appendage.

19. The method of claim 15, wherein the retention member comprises a tissue penetrating shaft configured to penetrate and be secured to tissue of the left atrial appendage and the device for occluding a body cavity is at least partially deployed by penetrating the tissue of the left atrial appendage with the tissue penetrating shaft such that the tissue penetrating shaft is mechanically secured thereto.

20. A method of occluding a left atrial appendage as in claim 15, wherein the occluding member comprises a self expandable frame.

21. A method of occluding a left atrial appendage as in claim 20, further comprising a barrier on the frame.

22. A method of occluding a left atrial appendage as in claim 21, wherein the barrier comprises a polymer selected from the group consisting of Dacron, Nylon, TFE, PTFE, ePTFE, and polyurethane.

23. A method of occluding a left atrial appendage as in claim 21, wherein the barrier has a pore size of up to about 0.04 inches.

24. A method of occluding a left atrial appendage as in claim 15, wherein the retention member comprises a self expandable wire structure.

25. A method of occluding a left atrial appendage as in claim 24, further comprising a polymer on the wire structure.

26. A method of occluding a left atrial appendage as in claim 15, wherein the advancing step comprises advancing the delivery catheter through the right femoral vein.

27. A method of occluding a left atrial appendage as in claim 15, wherein the advancing step comprises advancing the delivery catheter to the left atrial appendage intraoperatively.

28. A method of occluding a left atrial appendage as in claim 15, wherein the device comprises a plurality of tissue engagement members, and the method further comprises the step of engaging tissue with the tissue engagement members.

29. A method of occluding a left atrial appendage as in claim 1, wherein the device comprises a plurality of tissue engagement members, and the method further comprises the step of engaging tissue with the tissue engagement members.

* * * * *

United States Patent [19]

Herms et al.

[11] **Patent Number: 4,817,600**

[45] **Date of Patent: Apr. 4, 1989**

[54] **IMPLANTABLE FILTER**

[75] Inventors: **James K. Herms**, Watertown; **Gaillard R. Nolan**, Acton; **Jonathan McGrath**, Canton; **Mark J Tolkoff**, Brookline, all of Mass.

[73] Assignee: **Medi-Tech, Inc.**, Watertown, Mass.

[21] Appl. No.: **53,354**

[22] Filed: **May 22, 1987**

[51] **Int. Cl.**[4] **A61B 17/00**

[52] **U.S. Cl.** ..... **128/303 R**; 128/345

[58] **Field of Search** ..... 128/1 R, 303 R, 325, 128/345

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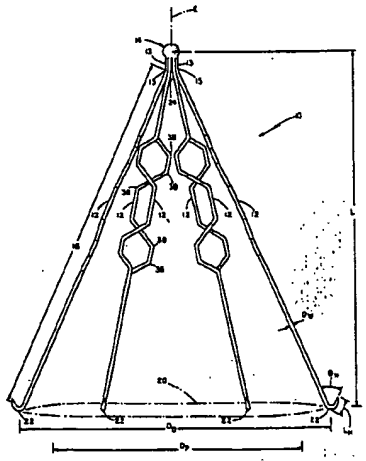
Primary Examiner—Stephen C. Pellegrino

[57] **ABSTRACT**

A blood clot filtration device, for implantation percutaneously, for preventing movement of blood clots within a blood vessel. The device has a head and a plurality of legs extending therefrom. The legs include a first linear leg portion of predetermined length emanating distally from the head generally parallel to the axis of the device; a second multi-angled leg portion of relatively greater length extending generally outwardly from the distal end of the first linear leg portion at an acute angle to the axis, to form, with other second leg portions, a conical aspect, the second leg portion having a series of discrete linear segments arrayed generally tangent to a cone defined by the second leg portions of the set of legs; and a hook portion at the distal end of each the leg extending outwardly, away from the axis in a manner for engaging the blood vessel to fix the position of the device therewithin. The configuration of the legs, including the first linear portion, and the use of a high strength titanium alloy for the head, formed by fusing, and legs produces a filter which is able to tolerate severe compression for introduction percutaneously through a small sheath without yielding. Preferably a central wire segment is disposed axially, with the first linear leg portions of the filter disposed closely thereabout.

18 Claims, 5 Drawing Sheets



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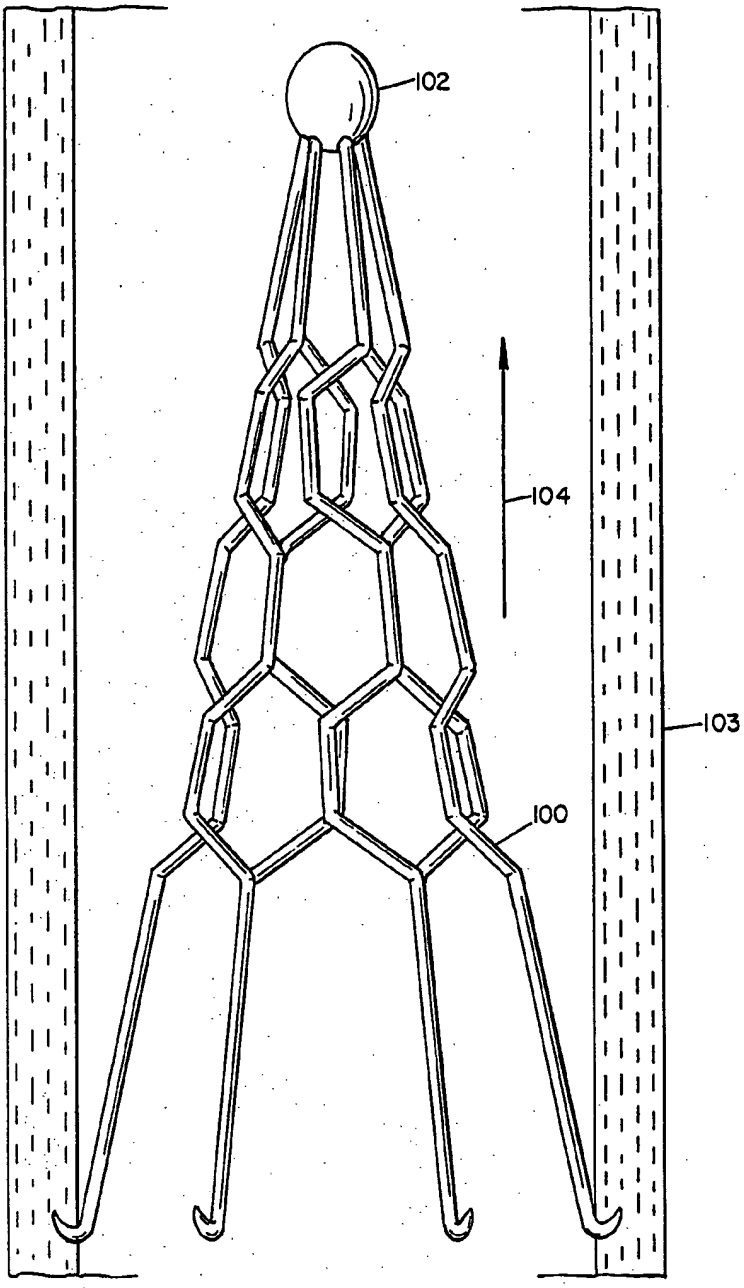

PRIOR ART

FIG 1

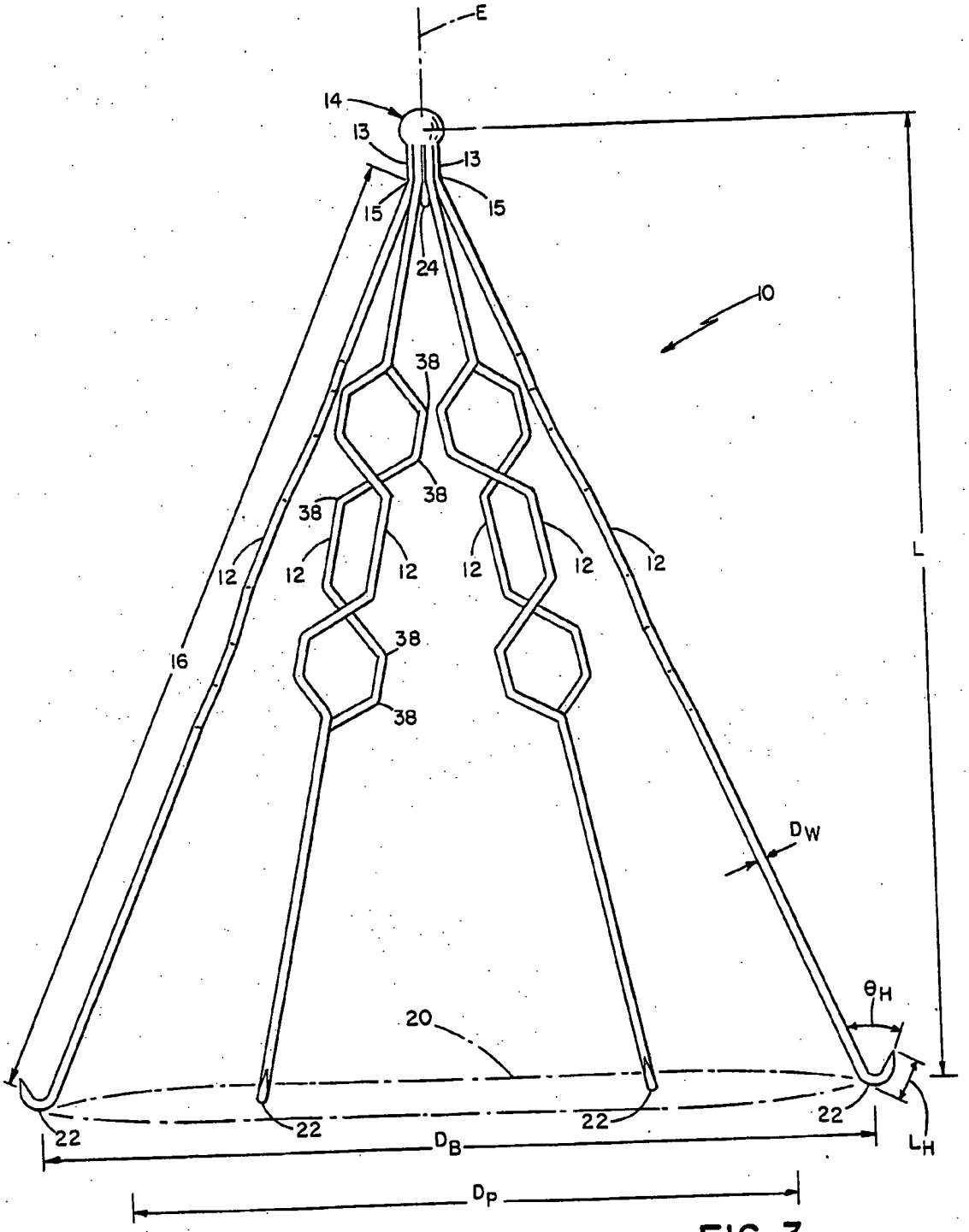
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FIG 3

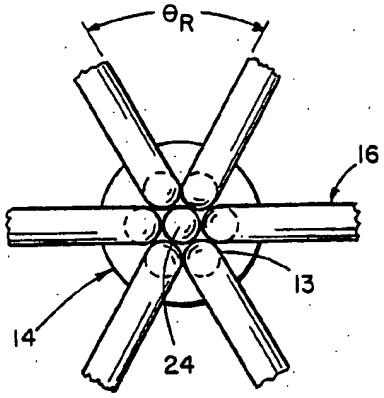


FIG 4

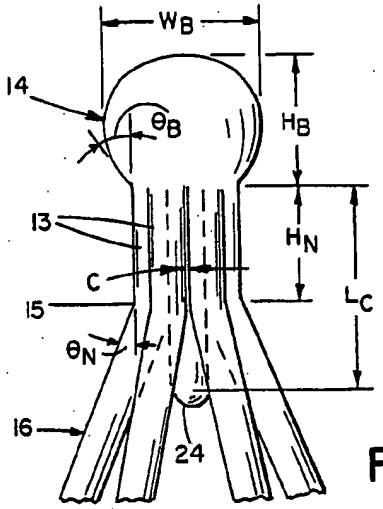


FIG 5

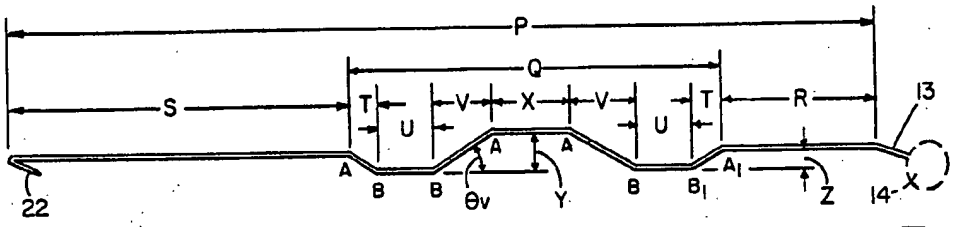
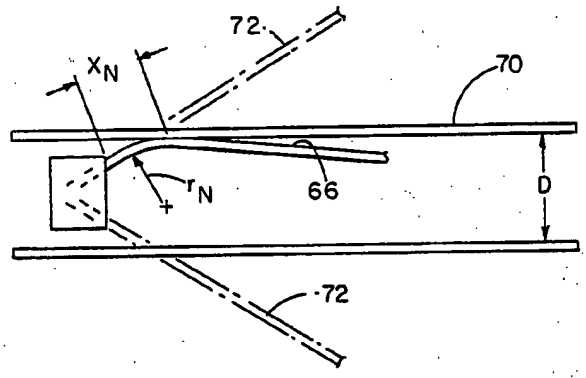


FIG 7



PRIOR ART

FIG 8A

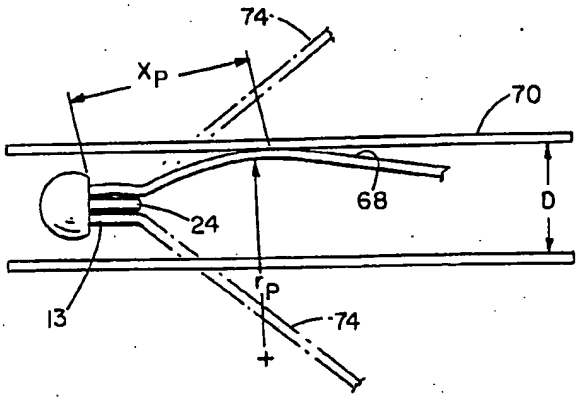
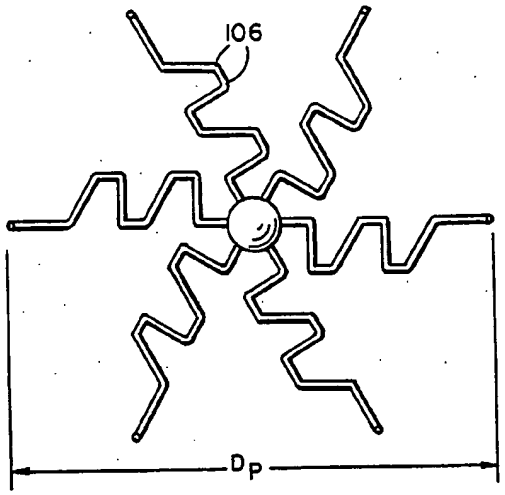


FIG 8B



PRIOR ART

FIG 2

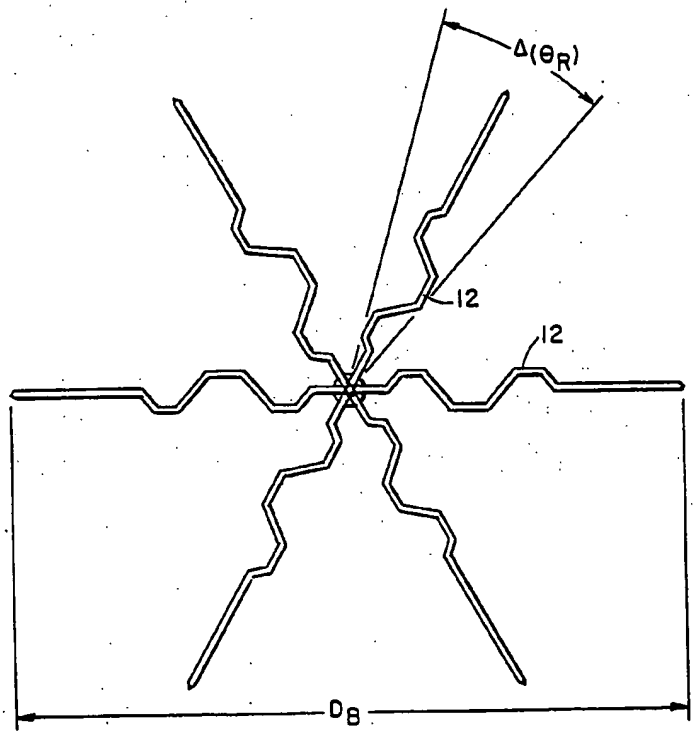


FIG 6

FIG 9

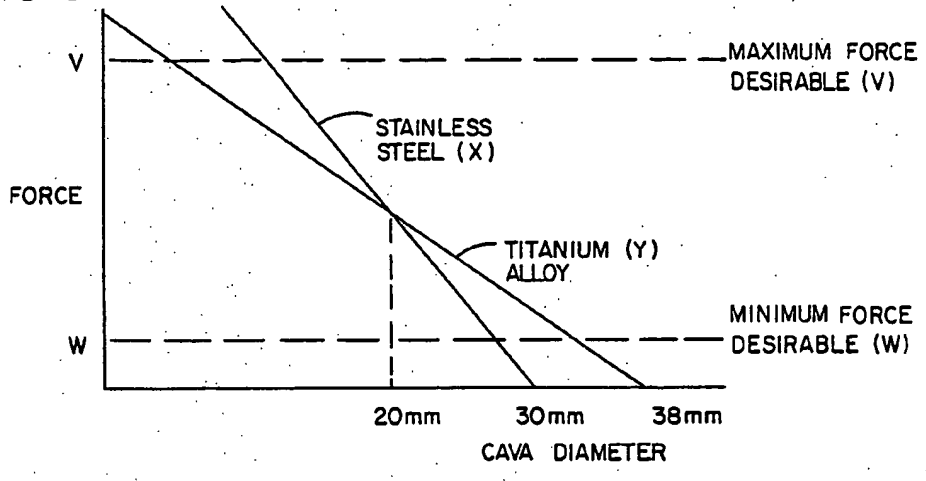


FIG 9A

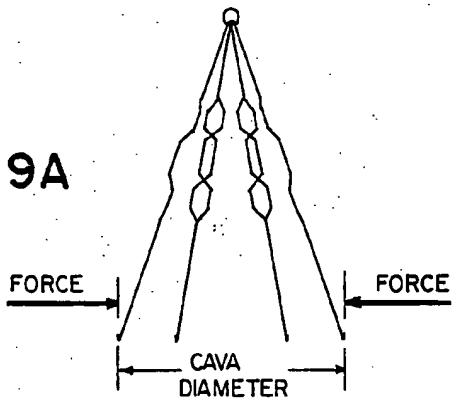
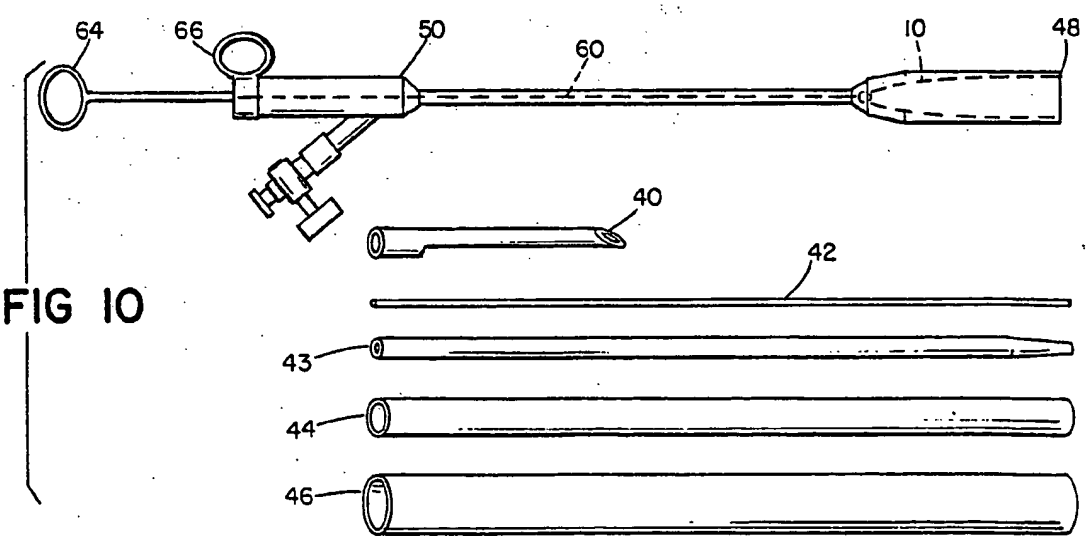


FIG 10



IMPLANTABLE FILTER

BACKGROUND OF THE INVENTION

This invention relates to blood clot filters of the permanent metallic type, that may be placed in the inferior vena cava, one of the two main veins for returning blood to the heart. Their purpose is to stop large clots or thrombi from traveling, typically from the leg veins, through the inferior vena cava, to the heart. If such clots reach the lungs, they would occlude the flow of blood and possibly lead to death.

Filters of this type are typically formed of fine wire legs attached to a head or nose cone. The wire legs have a conical aspect in order to channel emboli (or clots) toward the center of the filter, to the nose cone near the apex of the filter. The filter thus may trap clots of approximately three millimeters or larger. The clot, depending on its age and nature, may stay permanently in the filter or may be resorbed by the body.

One blood clot filter of particular effectiveness is a prior commercial embodiment of Kimmell U.S. Pat. No. 3,952,747, sold by Medi-Tech Incorporated of Watertown, Mass., under the trademark GREENFIELD ®. The prior commercial Kimmell filter has stainless steel wire legs extending from a large head. According to Kimmell, the legs are arranged in a conical aspect, each leg bent to form a number of linear segments generally tangent about the conical aspect to increase the filtering effect. When the filter is inserted into a blood vessel, the head and the apex of the cone are positioned downstream in the blood flow. The remote ends of the legs are positioned upstream in the blood flow and are engaged with the vessel wall.

Blood vessel filters have previously been introduced into a vessel surgically, by cutting down to and then into a vein, using surgical blades. The filter, confined within a metallic capsule, has been introduced through a catheter. Once in position, the filter has been dislodged from the capsule using a pusher, and the capsule and attached catheter removed. Typically, the surgical procedure has required two special teams of physicians, including a surgeon and a radiologist, and it is not uncommon for the procedure to take up to 2 hours.

More recently, certain filters have been inserted percutaneously. The advantages of this technique include reduced trauma and shortened operating time. The applicability of this technique has been limited in the case of the preferred Kimmell type of filter.

SUMMARY OF THE INVENTION

The present invention features a filter of the Kimmell type having significant improvement that, e.g., enables its percutaneous introduction over a wide range of patient population and inferior vena cava size. In one aspect the invention features a filter of the type mentioned having a head; a plurality of legs having divergent leg portions, each leg secured at one of its ends to the head, each having securing means on its end distal with respect to the head and at least one generally U-shaped bend intermediate its end, with the improvement that each leg further comprises a first linear leg portion between the head and the divergent leg portion, the first linear leg portion having a predetermined length emanating distally from the head, the first linear leg portion being arranged generally parallel to the axis of the device.

According to another aspect of the invention, first leg portions emanating from the head closely surround a central member, the head being formed of the metal of the ends of the first leg portions and of the central member, the central member serving to provide lateral support when the legs are compressed together.

In preferred embodiments, the legs and the head are formed of a titanium alloy, preferably the alloy being at least 50 percent by weight titanium and the head comprises a bead formed by fusing the legs.

According to another aspect of the invention, with the head comprising a bead formed by fusing the legs, each of the legs comprises: (a) a first linear leg portion of predetermined length emanating distally from the head in a direction upstream of the direction of blood clot movement within the vessel, the first linear leg portion arranged generally parallel to the axis of the device, (b) a second, multi-angled leg portion of relatively greater length than the first linear leg portion, the second, multi angled leg portion extending generally outwardly from the distal end of the first linear leg portion, at an acute angle to the axis to form, with second, multi angled leg portions of other legs, a conical aspect, the second, multi-angled leg portion comprising a series of discrete linear segments arrayed generally tangent to a cone defined by the set of second, multi-angled leg portions, and (c) a hook portion at the distal end of each of the legs, extending outwardly, away from the axis, in a manner for engaging the blood vessel wall to fix the position of the device therewithin, and the legs and the head being formed of a titanium alloy.

In further preferred embodiments of the invention, the diameter of the bead that forms the head is of the order of less than about 3 mm; the diameter of the base of the conical aspect of the device measured at the intersection of the second, multi-angled leg portions and the hook portions is between about 28 and 48 mm, preferably the device is adapted to be introduced into the blood vessel within a tubular cavity of an introducing cartridge, the cavity within which the device is disposed for insertion having an inner diameter of the order of between 3 to 4 mm; the length of the first linear leg portion is of the order of about 0.5 to 2 mm; and the overall length of the device along the axis, within the blood vessel, is of the order of about 50 mm.

According to another aspect of the invention there is provided a blood clot filtration device adapted for implantation percutaneously via a tubular cavity of an introducing cartridge, into a blood vessel of the body, the cavity within which the device is disposed for insertion having an inner diameter between about 2 and 4 mm, the filtration device comprising: a head and a plurality of legs extending therefrom, the head comprising a bead formed by fusing the legs and having a diameter of the order of less than about 3 mm, each of the legs comprising: (a) a first linear leg portion of predetermined length emanating distally from the head in a direction upstream of the direction of blood clot movement within the vessel, the first linear leg portion arranged generally parallel to the axis of the device, the predetermined length being of the order of about 0.5 to 2 mm, (b) a second multi angled leg portion of relatively greater length than the first linear leg portion, the second, multi angled leg portion extending generally outwardly from the distal end of the first linear leg portion, at an acute angle to the axis to form, with the second, multi-angled leg portions of other legs, a conical aspect having a diameter at the base of between about 30 and

50 mm, the second, multi-angled leg portion comprising a series of discrete linear segments arrayed generally tangent to the cone defined by the second, multi-angled leg portions, and (c) a hook portion at the distal end of each leg extending outwardly, away from the axis, in a manner for engaging the blood vessel wall to fix the position of the device therewithin, and the legs and the body being formed of a titanium alloy, the overall axial length of the device in position within the blood vessel being of the order of about 50 mm.

The blood clot filtration device of the invention, without detrimental yielding of the metal or loss of function, can be confined to a very narrow diameter for insertion percutaneously using narrow catheter tubes, e.g., 11 French or 3.7 mm internal diameter; the original conical aspect of the legs is regained even after insertion via the narrow catheter tube; and the legs exert appropriate force against the vessel walls upon positioning.

The filter achieves a filtering efficiency and capacity similar to that of the prior commercial Kimmell filter, retaining thromboemboli large enough to produce clinically significant pulmonary embolism. It passes a sufficient quantity of small thromboemboli to prevent either acute or insidious filter clogging, and permits lysis of the retained thromboemboli. Further, it helps to avoid the generation of new thrombi (or growth of retained emboli) from local stasis or turbulence in venous flow, in a wide range of diameters of inferior vena cavae.

Anchoring of the filter within a cava is achieved using approximating similar forces to those of the prior commercial Kimmell filter, but over an increased range of cavae sizes There is no proximal migration, even when severe mechanical forces are applied, nor distal migration, beyond the range exhibited by the prior commercial Kimmell filter. Radial penetration through adventitia is also within limits that have been acceptable historically. Further, it is believed that the filter can be maintained in situ for extended periods (of at least 8–10 years) without loss of the original chemical and mechanical properties, and with no corrosion, fatigue, or yielding, under even severe mechanical strain, and even in large diameter megacavae, e.g., up to 30 mm in diameter.

Other features and advantages of the invention will be apparent from the following description of the preferred embodiment, and from the claims.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The drawings will first briefly be described.

Drawings

FIG. **1** is a diagrammatic representation of a prior art filter as described in Kimmell U.S. Pat. No. 3,952,747, in situ; and

FIG. **2** is a plan view of the prior art Kimmell filter observed from above the head.

FIG. **3** is a side view of a preferred embodiment of the blood clot filtration device of the present invention;

FIGS. **4** and **5** are plan and side views respectively of the head area of the device;

FIG. **6** is a plan view of the device, observed from below the head;

FIG. **7** is a diagrammatic representation of one leg of the device;

FIGS. **8***a* and **8***b* are diagrammatic representations of the strain on a leg in the prior art device and the present invention, respectively;

FIG. **9** is a diagrammatic representation of the relationship between force exerted by filters of the invention and prior art filters, on a vena cava wall versus cava diameter;

FIG. **9***a* is a diagrammatic representation of the filter of the invention illustrating points of stress exerted on a cava; and

FIG. **10** is a diagrammatic plan view of a kit for inserting the filtration device of the invention percutaneously.

Prior Art

The prior art filter described in Kimmell U.S. Pat. No. 3,952,747, incorporated herein by reference, is shown in FIGS. **1** and **2**. Briefly, the prior art Kimmell filter has six legs **100** which are squeeze-fitted into a large head or nose cone **102**, all made from stainless steel. This filter has been inserted percutaneously using a 24 French catheter but usually has been inserted surgically. It is shown positioned in a cava **103**, of diameter about 20 mm, with head **102** downstream relative to blood flow, shown by arrow **104**. The leg bends, such as shown by number **106**, and their positioning are shown in FIG. **2**.

Structure of the Preferred Embodiment

Referring to FIGS. **3**, **4** and **5**, the preferred embodiment of the blood clot filtration device **10** of the invention consists of six legs **12** protruding from a head or nosebead **14**, both being of biocompatible titanium alloy beta III (ASTM grade 10, obtained from Ormco Corporation of Glendora, Calif., and designated Ti-11.5Mo-6Zr-4.5Sn, with major alloy elements molybdenum (10–13%), Zirconium (4.5–7.5%) and Tin (3.75–5.25%)). The legs **12**, e.g., wire of diameter D_W, about 0.018 inch (0.5 mm), each have: a first linear leg portion **13** lying parallel to axis E of the filter, for distance H_N, e.g., about 1 mm, a nose bend **15**, a second multi angled leg portion **16** of relatively greater length than the first linear leg portion, angling outwardly from the distal end of the first leg portion away from axis E, to define, with other second leg portions, an imaginary cone with base **20**, shown as dotted lines; and outwardly directed hooks **22**. The second leg portions **16** consist of a series of discrete linear segments arrayed generally tangent to the surface of the imaginary cone in a manner to increase the efficiency of the filtering effect. The diameter of the base of the filter is D_B, about 38 mm, and the overall length of the filter is L, about 50 mm. The linear leg portions **13** of all of the legs are closely arranged in a hexagonal pattern about central leg stub or segment **24** and the ends of all of these legs are joined at the apex in proximal head or nose bead **14**, formed by fusing the ends of legs **12** and central leg stub **24** together.

Referring to FIG. **4**, the six legs **16** are located at angle θ_R apart, about 60°, with maximum clearance between the wires, e.g. about 0.002 inch (0.05 mm). The width of the resulting nose is W_N about 0.06 inch (1.5 mm). Nose bead angle θ_N at nose bend **15** is about 23° and bead reinforcement angle θ_B is less than 35°. Referring to FIGS. **6** and **7**, leg **12** has maximum extensions $\Delta(\theta_R)$ of about 13°. The minimum radial distance from nose bead **14** to first concave edge A_1, is 0.03 inch (1.66 mm) and to first convex edge B_1 is about 0.08 inch (2.0 mm). Total leg length P is about 1.85 inch (47 mm), and total bent span Q is about e.g., 0.85 inch (22 mm). Unbent lengths R and S are about 0.32 inch, and 0.72 inch

(8.13 and 18.29 mm), respectively, and regions T, U, V, and X about 0.66, 0.12, 0.13, and 0.16 inch (16.7, 3.05, 3.3 and 4.06 mm), respectively, with angle θ_V about 40°. Distances Y and Z are respectively about 0.11 and 0.055 inch (2.79 and 1.40 mm).

Referring to FIG. 3, nose bead 14 of percutaneous filter 10 is formed by the molten metal of six legs 12 and leg stub 24 as they melt. Leg stub 24 is of length L_C, for example, about 2 mm. The six legs and leg stub are held in a fixture and are fused (e.g., by cast or arc welding) at the point where the legs meet, so that, under the influence of surface tension, the legs melt to form a small, solid spherical bead 14. The nose bead has a diameter W_B, about 2 mm, and height H_B, about 0.07 inch (1.8 mm).

The wires forming legs 12 are formed into first linear portion 13, second multi angled portion 16 and hook 22 against a steel guide in such a way that there is an alternating bend circumferentially oriented to produce a characteristic conical structure. Hook 22 has length L_H, about 1.8 mm, and is angled at angle θ_H, about 34°. The bends 38 in leg wires 12 are formed by bending the wires at an angle of 130°–150°. Hook 22 is formed mechanically by bending the distal end of wire 12 over a mandrel. Hook 22 is then sharpened on three sides against an abrasive wheel. Nose bend 15 is made to form first linear portion 13 near to bead 14, parallel to axis E of filter 10. The leg 12 then bends slightly outwardly on the major angle of the cone and passes through a series of bends as described above.

Diameter D_B and the length of first linear portion 13, from nose bend 15 to nose 14, as so determined, allows the filter to fit into a small diameter carrier tube, e.g., of approximately 12 French (inner diameter of about 3.7 mm), and still be able to spring open to the full diameter of the appropriate cava (10–30 mm). Diameter D and length A of the first linear portion 13 are selected relative to the overall length of the filter and the desired base diameter so the legs have sufficient spring force to engage the wall of the cava, but with force not so strong as to present a danger of rupture to the cava. If bead 14 and hook 22 are regarded as two ends of a beam, by selecting an appropriate distance H_N, e.g., about 1 mm, movement of hook 22 towards axis E, e.g., in compressing the filter for insertion into the blood vessel with a small diameter cartridge, applies stress to both nose bend 15 and the site of attachment of leg 12 to nose bead 14. Due to the arrangement shown, the stress is distributed over a large area, and the likelihood of permanent deformation is made less than in prior art filter devices. (Were the metal to yield the filter might become too small in diameter to engage the walls of a cava at all.)

One of the advantages of nose extension 13 is illustrated in FIGS. 8A and B. FIG. 8A represents a filter compressed within a tube without extension 13, FIG. 8B similarly represents a filter with extension 13. Referring to the figures, solid lines 66 and 68 inside tube 70, of inner diameter, D, about 11 French, represent the filter legs when bent to fit into tube 70; dotted lines 72, 74 outside the tube represent the filter in its non compressed configuration. The corresponding lever arms X_N and X_P and radii of curvature r_N and r_P are shown. Without extension 13, X_N and r_N are small and thus compressive forces on bent wire 66 are great, and distortion of the wire is likely. With extension 13, X_P and r_P are large and the forces on wire 68 are small, with little chance of permanently deforming the wire. Shear and bending stresses are much lower for FIG. 8B than FIG. 8A, so yielding of wire 68 is unlikely.

The titanium alloy used to construct the preferred embodiment has about three times as much elasticity as other possible alloys such as stainless steel and thus help to avoid unwanted permanent deformation. Referring to FIG. 9, curves X and Y describe the relationship between stress exerted upon tissue by a stainless steel filter (curve X) and a titanium filter (curve Y) and the cava diameter in which the filter is placed (FIG. 9*a*). Both curves roughly describe a straight line intercepting at the optimal stress value in an average cava diameter of 20 mm. From FIG. 9, it can be calculated that if a stainless steel filter of an initial diameter of about 30 mm were released into a cava whose diameter were 30 mm, it would rest there without exerting any stress on the cava wall. As the size of the cava decreases in diameter, the force on the cava wall would increase linearly. In contrast, the equivalent titanium filter of the present invention has a resting diameter of about 38 millimeters. The curve relating force to the diameter of the filter at rest is also a straight line (curve Y, FIG. 9), but one which is less steep than that for stainless steel. The limits to the force that can be exerted against a cava are shown at points V, W in FIG. 9. If the force exerted by a filter on a cava is on the low side, the filter would be less secure against incidental movement, e.g., due to movement by the patient or due to an embolism caught in the filter. If the force is on the high side, there is a risk of perforation of the wall of the cava by the filter. The advantage of the titanium filter is that, because its resting diameter is greater, it exceeds the desirable minimum force earlier than the stainless steel filter and thus can be used for larger cava than stainless steel filters. On the other hand, when the titanum filter is in a smaller cava, it exerts less force than the stainless steel filter on the walls of the cava. Thus, there is less risk of perforation of smaller cava diameters.

A further advantage of the titanium alloy filter is that it has a high tolerance to mechanical strain. This allows a filter of the invention to be inserted into a cartridge of smaller diameter than the equivalent prior art stainless steel filter, and thus inserted into a cava using a narrower catheter. Thus, the filter of the invention can be readily inserted percutaneously.

Referring to FIG. 10, a kit for percutaneous insertion of the filtration device of the invention includes a guidewire 42, catheters 43, 44, sheath 46 and needle 40 For percutaneous insertion, the vein is punctured with needle 40. Guidewire 42 is inserted into the vessel through the needle. Tapered catheter 43, up to 8 French in diameter, is pushed into the vein, over the guide wire. Slightly larger catheter 44, up to 10 to 12 French, is slid coaxially over the first and is used to dilate the tissue and the vein. A tapered catheter, with a thin-walled sheath 46, is then placed over this catheter and the inner catheters and guidewire removed, leaving the sheath behind. The sheath acts as an access to permit the insertion of a cartridge 48 holding the filter 52. Sheath 46 has a thin wall so that catheter 44 fits snugly inside of sheath 46 and they can travel together as a single unit. Sheath 46 is constructed of high density polyethylene and is slippery so that the friction between it and the cava is reduced. Cartridge 48 with filter 10 is introduced through sheath 46. Sheath 46 should be flexible enough so that it doesn't kink, with, e.g., an inside dimension of 12.6 French and an outside dimension between 13 and 14 French. Also provided in the kit is a filter delivery

system 50 for delivery of the catheter. The dotted line within cartridge 4 shows the orientation of the filter 10, in the orientation where the hooks are ready to come out first, i.e., for introduction into a jugular vein. Pusher 60 is solid and is used to discharge the filter into location in a cava. Once the filter in the sleeve is in an appropriate position, the filter is pushed out of the sleeve using pusher 60. The legs of the filter will spring outward and engage the cava walls, thus holding the filter in position.

Comparison with Prior Commercial Kimmell Filter

The percutaneous filter of this invention can achieve a filter mesh between 75% and 125% of that of the prior commercial Kimmell filter, when both are confined inside a 20 mm inner diameter cylinder, with equivalent orientation (filter axis to cylinder axis). The leg wires are thus able to filter blood passing through the filter and catch clots of a desired size.

The range of arc $\Delta(\theta_R)$ (FIG. 6) described by the most proximal set of legwire bends is preferably reduced to less than 80% of $\Delta(\theta_R)$ for the corresponding bends in the prior commercial Kimmell filter. This reduces legwire interferences that otherwise would impose large flexural strains at the head of the filter during leading into the narrow-bore (e.g., 3.7 mm inner diameter) carrier 48. The flexural elasticity (resilience) achievable by this filter is at least 40% greater than that of the prior commercial Kimmell filter, for example, the flexural yield strain of the legwire alloy is preferably greater than 1.8%, as in high yield strain titanium alloys. This latter feature enables bending the filter legs towards the central axis, E (FIG. 3), by at least 21.6°, whilst the prior commercial Kimmell filter legs are bent in by only about 15.0°, during loading. Moreover, the legwire alloy has a linear (i.e., a proportional or elastic) relationship of stress vs. strain extending to above 1% deformation. That is, the legwire alloy remains elastic even during, for example, elongation by more than 1%.

The maximum strain concentration in the percutaneous filter structure (during loading, and when the filter is within a cava) can be significantly lower than that in the structure of the prior commercial Kimmell filter. The strain concentration at the proximal end of the filter legs is achieved by, a filter nose (13, in FIG. 3), of minimal height H_N (FIG. 3), and a filter bead (14, in FIG. 3); the bead reinforcement angle θ_B (FIG. 3) is preferably reduced below the nose-cone "reinforcement angle" of 90° found in the prior commercial Kimmell filter; the maximum clearance C (FIG. 3) between nose-wires is minimized; and the close-packed center wire (leg stub 24, in FIG. 5) maintains the alignment of the array of wires and serves as an advantageous fulcrum during deflection, helping to reduce stress, to avoid yielding during maximum compression. Furthermore, the six filter legs may be negatively curved so that the cone shape described by the legs is slightly concave (cusp-like). Upon insertion into a 20 mm vena cava, the slight concave bend is effectively straightened out.

In order to insure long term mechanical stability and safe anchorage in normal vena cava (having a diameter of about 20 mm) or larger megacavae; the invention achieves anchoring dilational loads and forces at the hook tips similar to those produced by the prior commercial Kimmell filter in normal cava. Preferably, the filter base diameter D_B (FIG. 3) is 30–50 mm (typically 38 mm), compared to diameter D_P of the prior commercial Kimmell filter, e.g., about 30 mm.

A low modulus alloy is important to optimally satisfy the above requirements preferably one which resists corrosion and fatigue, even after severe cold-forming or hot-forming and cold-joining or hot-joining operations.

Other embodiments are within the following claims.

What is claimed is:

1. In a blood clot filtration device for filtering solid and semi-solid materials from a liquid moving along a vessel axis of a tubular vessel, said filtration device having a device axis and comprising:

a head; and

a plurality of legs having divergent leg portions, each said leg secured at one of its ends to said head and each having securing means on its end distal with respect to said head; and at least one generally U-shaped bend intermediate its end,

the improvement wherein,

said legs further comprises a first linear leg portion between said head and said divergent leg portion, said first linear leg portion having a predetermined length emanating distally from said head and, said first linear leg portion being arranged parallel to said device axis of said filtration device.

2. In a blood clot filtration device for filtering solid and semi solid materials from a liquid moving axially in a tubular vessel, said filtration device comprising;

a head; and

a plurality of legs having divergent leg portions, each said leg secured at one of its ends to said head and each having securing means on its end distal with respect to said head; and at least one generally U-shaped bend intermediate its end;

the improvement wherein,

each of said legs further comprises a first leg portion between said head and its divergent leg portions, said first leg portions closely surrounding a central member, said head formed of the ends of said first leg portions and the end of said central member, said central member serving to provide lateral support to said first portions emanating from said head when said legs are compressed together.

3. The blood clot filtration device of claim 1 or 2 wherein said legs and said head are formed of a titanium alloy.

4. The blood clot filtration device of claim 3 wherein said alloy is at least 50 percent by weight titanium.

5. The blood clot filtration device of claim 1 or 2 wherein said head comprises a bead formed by fusing said legs.

6. The blood clot filtration device of claim 1 or 2 wherein the legs at said head closely surround a central wire segment.

7. The blood clot filtration device of claim 4 or 6 wherein the diameter of said bead forming said head is of the order of less than about 3 mm.

8. The blood clot filtration device of claim 1 or 6 wherein the diameter of the base of said conical aspect of said device measured at the intersection of said second, multi-layered leg portions and said hook portions is between about 30 and 50 mm.

9. The blood clot filtration device of claim 7 wherein said device is adapted to be introduced into said blood vessel within a cylindrical cavity of an introducing cartridge, said cavity within which said device is disposed for insertion having an inner diameter between about 3 to 4 mm.

10. A blood clot filtration device adapted for implantation percutaneously, of the kind for preventing movement of blood clots within a blood vessel comprising:

a head and a plurality of legs extending therefrom,

said head comprising a bead formed by fusing said legs,

said legs comprising:

(a) a first linear leg portion of predetermined length emanating distally from said head in a direction upstream of the direction of blood clot movement within said vessel, said first linear leg portion arranged generally parallel to the axis of said device,

(b) a second, multi-angled leg portion of relatively greater length than said first linear leg portion, said second, multi-angled leg portion extending generally outwardly from the distal end of said first linear leg portion, at an acute angle to said axis to form, with said second, multi-angled leg portions of other legs, a conical aspect, said second, multi-angled leg portion comprising a series of discrete linear segments arrayed generally tangent to a cone defined by the set of said second, multi-angled leg portions, and

(c) a hook portion at the distal end of each said leg extending outwardly, away from said axis, in a manner for engaging the blood vessel wall to fix the position of said device therewithin, and

said legs and said head being formed of a titanium alloy.

11. The blood clot filtration device of claim 1 or 7 wherein said length of said first linear leg portion is of the order of about 0.5 to 2 mm.

12. The blood clot filtration device of claim 1 or 7 wherein the overall length of said device along the axis, within said blood vessel, is of the order of about 50 mm.

13. A blood clot filtration device adapted for implantation percutaneously via a tubular cavity of an introducing cartridge, into a blood vessel of the body, of the kind for preventing movement of blood clots within said blood vessel, said cavity within which said device is disposed for insertion having an inner diameter of the order of between 2 to 4 mm, said filtration device comprising:

a head and a plurality of legs extending therefrom,

said head comprising a bead formed by fusing said legs and having a diameter of the order of less than about 3 mm,

said legs comprising:

(a) a first linear leg portion of predetermined length emanating distally from said head in a direction upstream of the direction of blood clot movement within said vessel, said first linear leg portion arranged generally parallel to the axis of said device, said predetermined length being of the order of about 0.5 to 2 mm,

(b) a second multi-angled leg portion of relatively greater length than said first linear leg portion, said second, multi-angled leg portion extending generally outwardly from the distal end of said first linear leg portion, at an acute angle to said axis to form, with second, multi angled leg portions of other legs, a conical aspect having a diameter at the base of between about 28 and 48 mm, said second, multi-angled leg portion comprising a series of discrete linear segments arrayed generally tangent to said cone defined by said second, multi-angled leg portions, and

(c) a hook portion at the distal end of each said leg extending outwardly, away from said axis, in a manner for engaging the blood vessel wall to fix the position of said device therewithin, and

said legs and said body being formed of a titanium alloy,

the overall axial length of said device in position within said blood vessel being of the order of about 50 mm.

14. The device of claim 6, 7, or 13 wherein said device further comprises a central wire segment positioned axially, with said first linear leg portions disposed thereabout.

15. In a blood clot filtration device for filtering solid and semi-solid materials from a liquid moving axially in a tubular vessel, said filtration device comprising:

a head; and

a plurality of legs having divergent leg portions, each said leg secured at one of its ends to said head and each having securing means on its end distal with respect to said head; and at least one general U-shaped bend intermediate its ends, the legs being formed of a high strength titanium alloy having a linear relationship of stress versus strain extending to above 1 percent deformation of said alloy, and said head being formed by fusing together corresponding ends of the legs, said legs, under a no-stress condition, conforming to a large base cone of diameter of about 30 mm or more, the legs being capable of such elastic deformation that the filter can be collapsed into a capsule of about 12 French external diameter.

16. The filter of claim 15 wherein the base diameter to which the ends of the legs conform is 30 mm or larger.

17. The filter of claim 15 wherein said blood clot filtration device exerts a force against the tubular vessel when in place therein, said tubular vessel having a predetermined maximum force limit, said titanium alloy having an elasticity selected to exert less than said maximum force against said tubular vessel for a tubular vessel inner diameter substantially less than 20 mm.

18. In a blood clot filtration device for filtering solid and semi-solid materials from a liquid moving axially in a tubular vessel, said filtration device comprising;

a head; and

a plurality of legs having divergent leg portions, each said leg secured at one of its ends to said head and each having securing means on its end distal with respect to said head; and at least one generally U-shaped bend intermediate its ends, the legs being formed of a high strength titanium alloy having a flexural yield strain greater than 1.8%, and said head being formed by fusing corresponding ends of the legs, said legs, under a no-stress condition, conforming to a large base cone of diameter of about 30 mm or more, the legs being capable of such elastic deformation that the filter can be collapsed into a capsule of about 12 French external diameter.

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(12) **United States Patent**
Van Tassel et al.

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(45) **Date of Patent: Apr. 22, 2003**

(54) **BARRIER DEVICE FOR OSTIUM OF LEFT ATRIAL APPENDAGE**

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(58) **Field of Search** 604/500, 506–508, 604/104, 105, 106; 128/898; 606/200

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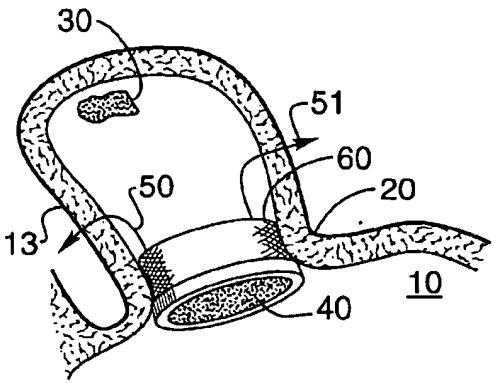
(57) **ABSTRACT**

A membrane applied to the ostium of an atrial appendage for blocking blood from entering the atrial appendage which can form blood clots therein is disclosed. The membrane also prevents blood clots in the atrial appendage from escaping therefrom and entering the blood stream which can result in a blocked blood vessel, leading to strokes and heart attacks. The membranes are percutaneously installed in patients experiencing atrial fibrillations and other heart conditions where thrombosis may form in the atrial appendages. A variety of means for securing the membranes in place are disclosed. The membranes may be held in place over the ostium of the atrial appendage or fill the inside of the atrial appendage. The means for holding the membranes in place over the ostium of the atrial appendages include prongs, stents, anchors with tethers or springs, disks with tethers or springs, umbrellas, spiral springs filling the atrial appendages, and adhesives. After the membrane is in place a filler substance may be added inside the atrial appendage to reduce the volume, help seal the membrane against the ostium or clot the blood in the atrial appendage. The membranes may have anticoagulants to help prevent thrombosis. The membranes be porous such that endothelial cells cover the membrane presenting a living membrane wall to prevent thrombosis. The membranes may have means to center the membranes over the ostium. Sensors may be attached to the membrane to provide information about the patient.

22 Claims, 6 Drawing Sheets



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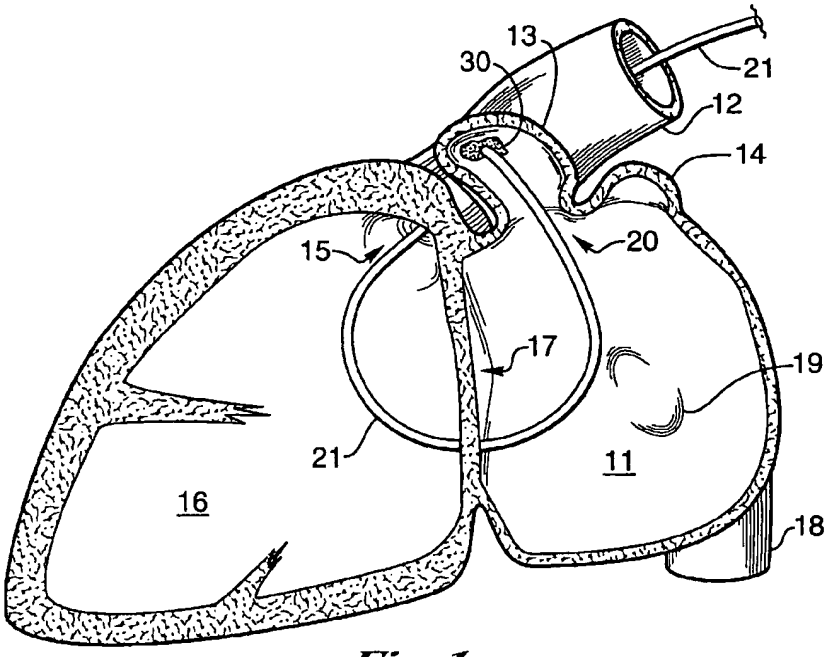
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Fig. 1

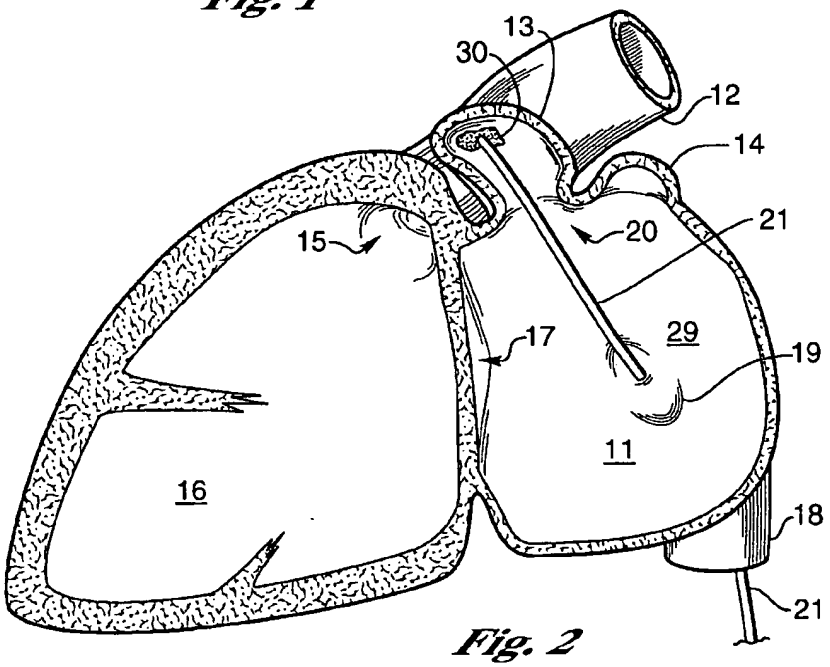
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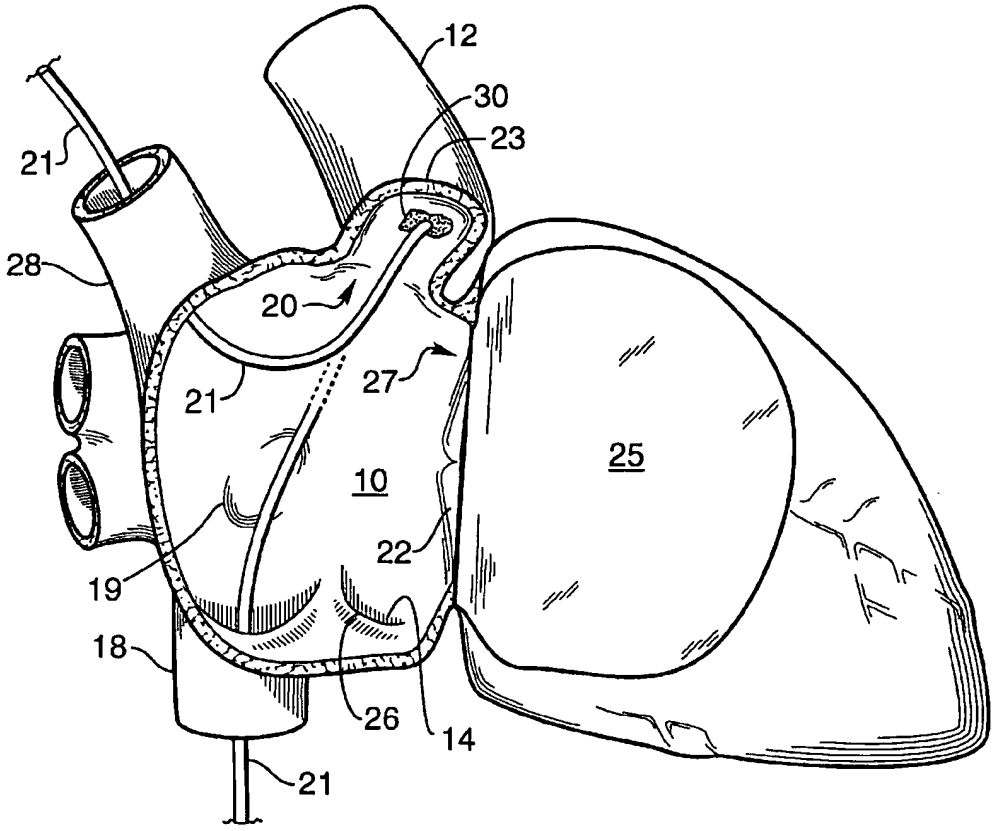
Fig. 2



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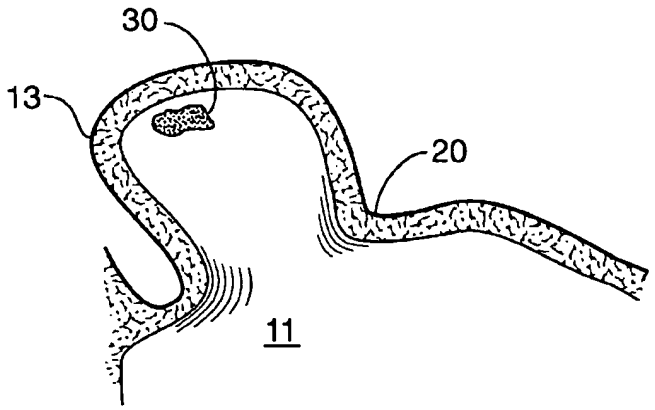

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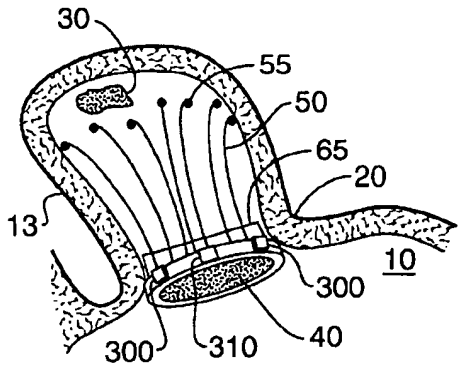

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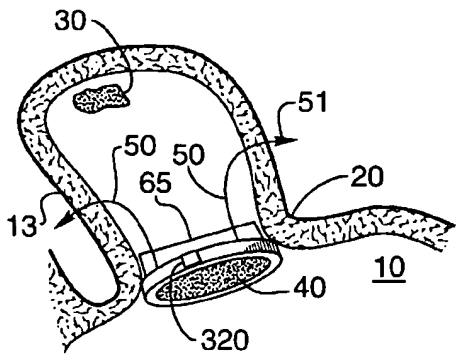

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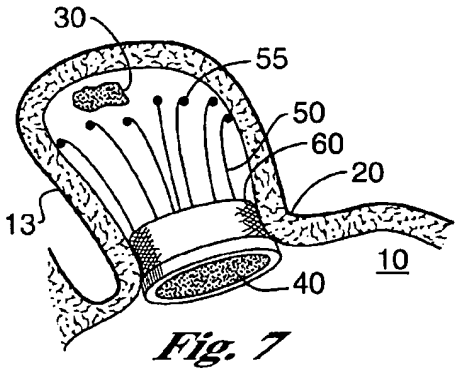

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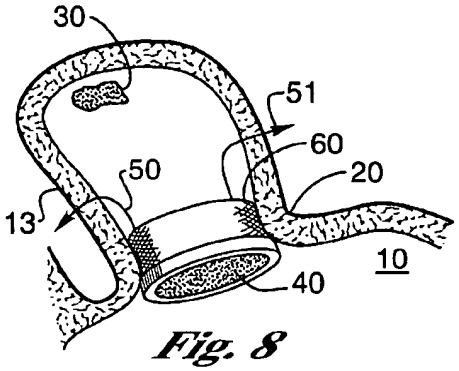

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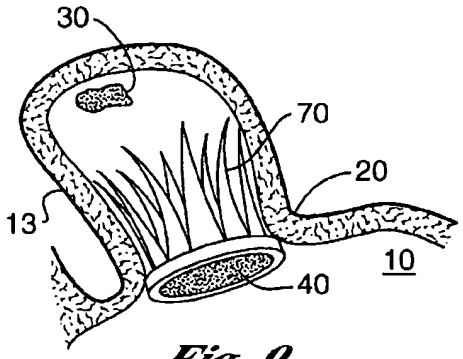

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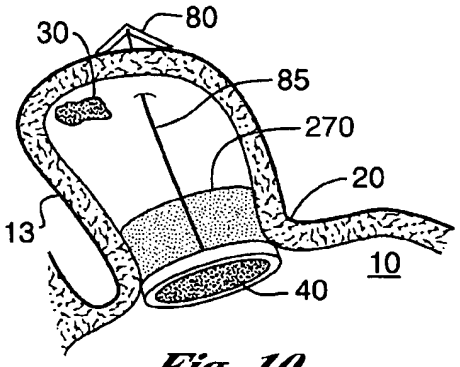

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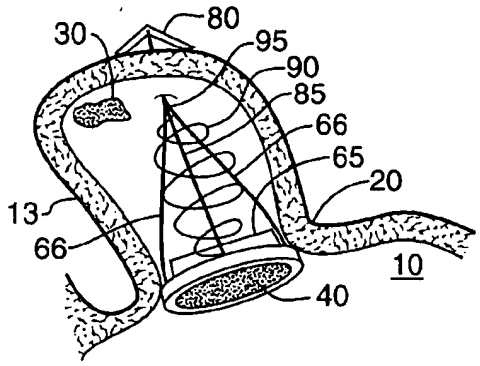

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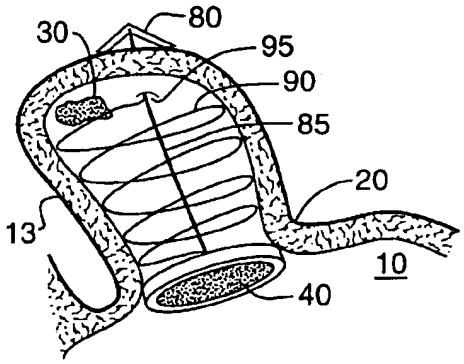

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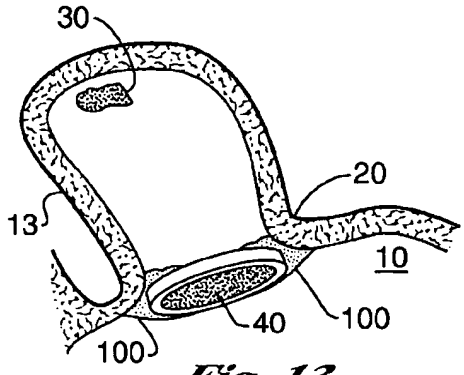

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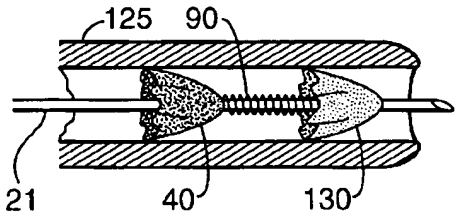

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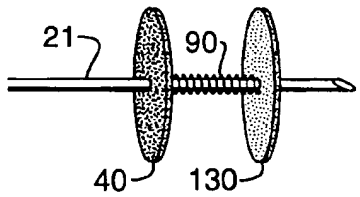

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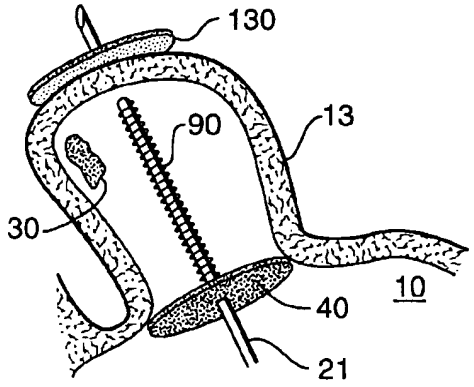

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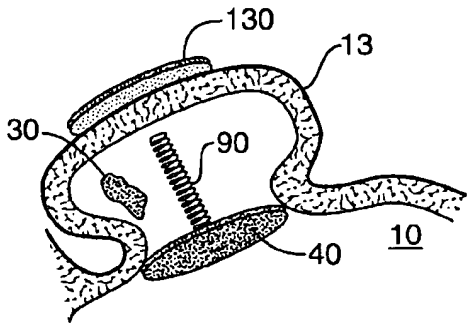
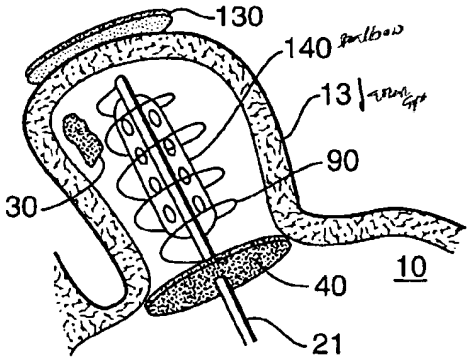


Fig. 17



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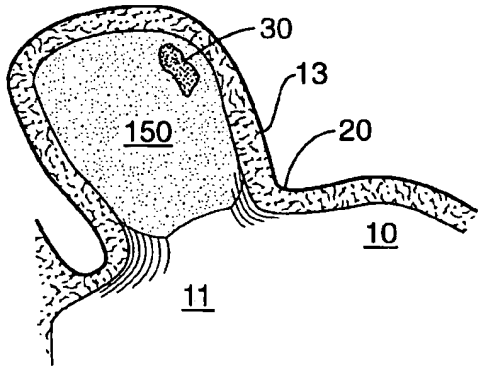


Fig. 19

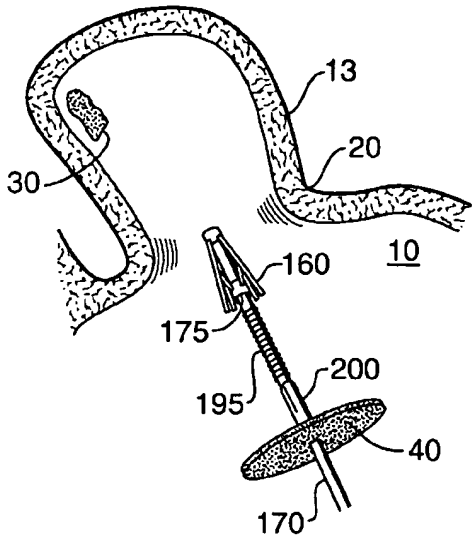
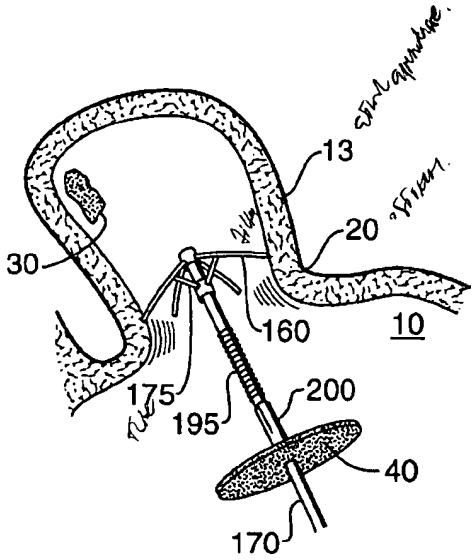


Fig. 20



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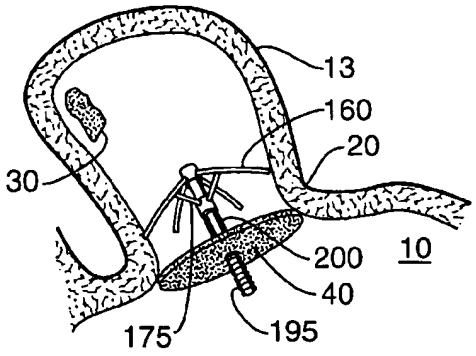

Fig. 22

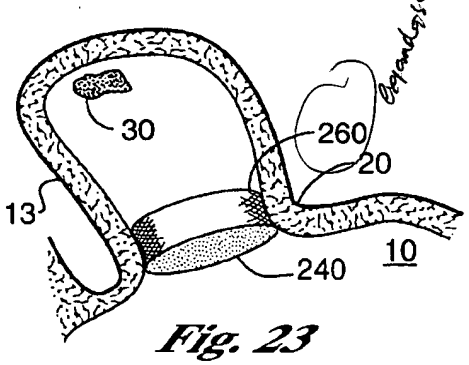

Fig. 23

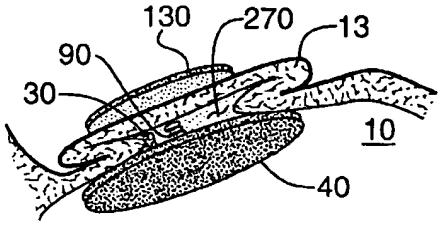

Fig. 24

BARRIER DEVICE FOR OSTIUM OF LEFT ATRIAL APPENDAGE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a membrane or plug structure applied to the ostium of an atrial appendage for preventing blood flow and physical connection between an atrium of the heart and the associated atrial appendage or appendages to isolate an atrial appendage and prevent thrombus leaving therefrom.

2. Description of the Related Art

There are a number of heart diseases (e.g. coronary artery disease, mitral valve disease) that have various adverse effects on the heart. An adverse effect of certain cardiac diseases, such as mitral valve disease, is atrial (or auricular) fibrillation. Atrial fibrillation may result in pooling of blood in the left atrial appendage. Blood pooling may also be spontaneous. When blood pools in the atrial appendage, blood clots can form and accumulate therein, build upon themselves, and propagate out from the atrial appendage into the atrium. These blood clots can then enter the systemic or pulmonary circulations and cause serious problems if they migrate from the atrial appendage and become free in the blood stream and embolize distally into the arterial system. Similar problems also occur when a blood clot extending from an atrial appendage into an atrium breaks off and enters the blood supply. Since blood from the left atrium and ventricle supply the heart and brain, blood clots from the atrial appendages can obstruct blood flow therein causing heart attacks, strokes or other organ ischemia. It is therefore necessary to find a means of preventing blood clots from forming in the atrial appendages and to prevent these blood clots, once formed, from leaving the atrial appendages to the heart lungs, brain or other circulations of the patient which can cause heart attacks or strokes or other organ ischemia

U.S. Pat. No. 5,865,791 relates to the reduction of regions of blood stasis and ultimately thrombus formation in such regions, particularly in the atrial appendages of patients with atrial fibrillation. More specifically, the invention relates to procedures and devices for affixing the atrial appendages in an orientation that prevents subsequent formation of thrombus. The invention removes the appendage from the atrium by pulling on it and putting a loop around it to form a sack of the atrial appendage and then cut off from the rest of the heart.

U.S. Pat. No. 5,306,234 relates to a method for surgically closing the passage between the atrium and the atrial appendage or severing the atrial appendage.

Other methods of treatment include surgically removing the atrial appendages to prevent blood stasis in the atrial appendages.

SUMMARY OF THE INVENTION

The invention provides a membrane or plug structure for preventing blood from entering the atrial appendages to form blood clots and prevents blood clots formed in the atrial appendages from exiting therefrom which may cause heart attacks, strokes and other embolic events. The membrane covers the ostium of the atrial appendage and effectively isolates it from the atrium. It may be larger than the ostium of the appendage, and extend over an area larger than the appendage ostium. It is percutaneously delivered to the ostium of the atrial appendage by a catheter and then expanded to cover the ostium and has a means to attach the membrane over the ostium. The membrane itself may be porous or non-porous. In the case of a porous membrane, it can become infiltrated with cells so that it becomes a "living" structure, and can develop an endothelial/endocardial lining to enable it in turn to become a non-thrombogenic surface. There are many means for fixing the membrane to cover the ostium of the atrial membrane. The membrane's attachment devices have a means for self-centering the membrane over the appendage ostium. The membrane may be glued on, or have a stents or prongs which pass through the ostium and extend into or through the atrial appendage. Alternatively an anchor in the wall of the atrial appendage may be tethered to the membrane for holding the membrane in place. Springs may also extend between the anchor and the membrane to hold the membrane against the ostium. The membrane may also be connected to a tether, elastic tether or spring and placed through the atrial appendage wall for holding the membrane against the ostium and may pull on the atrial appendage such that its volume is reduced or eliminated, trapping and isolating blood clots therein. Thrombin, activated fibrinogen, or other biologic filler may be placed in the appendage after it has been sealed, with the express purpose of clotting the blood in the appendage, yet preventing clots from escaping the appendage.

Part of the device may involve a suction apparatus to remove clots that are already in place. The membrane placement may require closure of an atrial septal defect created by the placement of this appendage occluder device.

Alternatively the membrane may be held in place by a coiled spring filling the volume of the atrial appendage. The membrane may also fill the atrial appendage itself preventing blood from entering or blood clots from leaving.

The membrane itself may be porous or non-porous. In the case of a porous membrane, it can become infiltrated with cells so that it becomes a "living" structure, and can develop an endothelial/endocardial lining to enable it in turn to become a nonthrombogenic surface. It thus can develop an endothelium and with time becomes highly biocompatible. It may be heparin-coated to prevent thrombus from forming on the membrane surface, immediately after placement and until it infiltrates with cells and/or develops an endothelial covering.

The device, when implanted in the atrial appendage, may also have the ability to perform electrical monitoring of the heart. This would consist of two or more electrical contacts placed apart on the device, and connected to signal conditioning circuitry for determination of cardiac features such as rhythm of the atria or ventricles. Another sensor on the device could measure pressure of the atria, atrial appendage, or ventricular end diastolic pressures (left or right) through the open mitral or tricuspid valves. A suitable telemetry system would be used to telemeter this important electrical and hemodynamic information non-invasively outside the patient. Also, memory could be present on the device in order to record the information for later recovery via non-invasive telemetry.

This device can also be used to close filstulae or connections elsewhere in the body, such as in the colon or bronchopulmonary systems. Another application of the device would be to seal and strengthen false aneuryms of the left ventricle by holding the membrane against the false aneurysm. The same principles apply, whereby the membrane is held against the fistulae or false aneurysm, held in place by the spring or prong mechanisms.

The device can also be used to chemically ablate the myocardial tissue of the atrial appendage in order to help limit or eliminate the electrical propagation of atrial fibrillation.

OBJECTS OF THE INVENTION

It is an object of the invention to reduce the volume of an atrial appendage to reduce the size of the region for potential blood stasis formation, and consequently the effective volume of the affected atrium.

It is an object of the invention to measure hemodynamics pressure (or flow), or electrical signals in the heart and telemeter them outside the body for diagnosis or monitoring.

It is an object of the invention to be able to close fistulae or connections elsewhere in the body, such as in the colon or bronchopulmonary systems.

It is another object of the invention for the membrane to be placed in a false aneurysm to strengthen this defect, and to avoid surgery.

It is an object of the invention to reduce the region of static blood in the atrial appendages and hence the thrombogenicity of the atrium.

It is an object of the invention to prevent blood clots from forming in the atrial appendages.

It is an object of the invention to replace the ostium of the atrial appendage with a non-thrombogenic, biocompatible surface that prevents blood clots from forming.

It is an object of the invention to provide a porous membrane surface which becomes lined with endothelial or endocardial cells.

It is an object of the invention to isolate the atrial appendage from the atrium proper and prevent communication through which thrombus could migrate.

It is an object of the invention to minimally invasively prevent blood clots from forming in the atrial appendages and escaping therefrom.

It is an object of the invention to provide a filter between the atrium and atrial appendage to prevent blood clots from flowing therebetween.

It is an object of the invention to fill the atrial appendage with a material to prevent blood clots from leaving the atrial appendage.

It is an object of the invention to remove thrombi from the atrium via suction or other means.

It is an object of the invention to provide a means for securing a membrane over the ostium of the atrial appendage that is colonized with cells and provide a highly biocompatible surface including but not limited to endothelialization.

It is an object of the invention to prevent thrombus by use of heparin or other anti-thrombogenic substance on or eluted from the membrane.

It is an object of the invention to seal the membrane with a substance injected into the atrial appendage.

It is an object of the invention to clot the blood inside of the atrial appendage after the membrane is in place with a substance injected into the atrial appendage.

It is an object of the invention to inject a substance into the sealed appendage to ablate the myocardial cells of the appendage, in order to limit the propagation of atrial fibrillation.

It is an object of the invention to ensure the membrane is centered over the ostium of the atrial appendage.

It is an object of the invention to accurately place the membrane over the ostium of the atrial appendage.

Other objects, advantages and novel features of the present invention will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a partial cross sectional view of a heart showing a catheter entering the left atrial appendage using a retrograde procedure from the aorta.

FIG. **2** is a partial cross sectional view of a heart showing a catheter entering the left atrial appendage using a transeptal procedure from the femoral vein or superior vena cava.

FIG. **3** is a partial cross sectional view of a heart showing a catheter entering the right atrial appendage from the jugular vein or optionally from the femoral vein.

FIG. **4** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage.

FIG. **5** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage with a porous membrane having flexible wire prongs with atraumatic bulbs to hold the membrane in place and electronics built into the membrane.

FIG. **6** is similar to FIG. **5** with the atraumatic bulbs removed so that the flexible wire prongs may puncture the atrium wall and secure the membrane to the atrial appendage and a centering rim added to the membrane.

FIG. **7** is a partial cross sectional view of a portion of a heart as in FIG. **5** with a stent portion between the membrane and the prongs.

FIG. **8** is the same as FIG. **7** with the atraumatic bulbs removed so that the flexible wire prongs may puncture the atrium wall and secure the membrane to the atrial appendage.

FIG. **9** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage with a porous membrane having a large expandable stent to hold the membrane in place.

FIG. **10** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage having an anchor and a tether to hold the membrane in place.

FIG. **11** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage having an anchor and a spring to hold the membrane in place, a centering rim on the membrane and a centering cable.

FIG. **12** is the same as FIG. **11** with the spring filling the atrium to help hold the membrane in place.

FIG. **13** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage with the membrane adhesively being held in place.

FIG. **14** is a partial cross sectional view of a delivery catheter having a disk, a spring and membrane therein.

FIG. **15** is a schematic view of a disk, spring and membrane after being expanded out of the delivery catheter of FIG. **11**.

FIG. **16** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage having a disk, a membrane and a spring therebetween.

FIG. **17** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage shown in a collapsed position.

FIG. **18** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage having a disk, a spring, a membrane and vacuum in the catheter.

FIG. **19** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage having a membrane material filling the atrial appendage.

FIG. **20** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage showing an umbrella folded for entering the atrial appendage.

FIG. **21** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage showing the umbrella opened in the atrial appendage to secure the umbrella into the wall of the atrial appendage.

FIG. **22** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage showing the umbrella and membrane sealing the ostium of the atrial appendage.

FIG. **23** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage showing a stent having a membrane for blocking the ostium of the atrial appendage.

FIG. **24** is a partial cross sectional view of a portion of a heart showing an atrium and its associated atrial appendage showing the atrial appendage reduced to a minimum volume by a disk and spring squeezing the appendage against a membrane.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Although atrial fibrillation results in pooling of blood in the left atrial appendage and the majority of use of the invention is anticipated to be for the left atrial appendage, the invention may also be used on the right atrial appendage and in general for any aperture in the body which needs to be blocked to prevent blood from flowing therethrough or therefrom.

As shown in FIG. **4** a thrombus **30** may occur from pooling of blood in the left atrial appendage **13** due to poor circulation of blood therein when the patient experiences atrial fibrillation. To prevent thrombus **30** from forming in the left atrial appendage **13** or to prevent thrombosis formed therein from leaving and entering the blood stream which may cause a heart attack, a stroke or ischemia, a membrane **40** is placed across the ostium **20** of the atrial appendage **13**. The membrane **40** can be made of Teflon®, felt, Dacron®, silicone urethane, Gortex®, metal fibers or biocompatible polymers.

The membrane **40** may be a porous membrane. Porous membranes may consist of a biocompatible polymer which is porous, having pore sizes ranging from 20–100 microns. The pores may also be larger or smaller in rare cases. The membrane may also be a porous metal or a metal mesh of fine fibers which permit ingrowth of cells and covering with endothelial cells. The membrane may be coated with anticoagulant, or elute the anticoagulant.

The porous membrane colonizes with cells from the heart and so walls off the ostium **20** so that blood can not flow into the left atrial appendage **13** to form thrombus **30** and more importantly no thrombus **30** formed can leave the left atrial appendage **13** to cause heart attacks, strokes or ischemia.

The membrane **40** placed over the ostium **20** should be antithrombotic. In order to make the membrane antithrombotic, heparin or other anticoagulants or antiplatelet agent may be used on the membrane **40**.

When porous membranes **40** are used which have an ingrowth of cells, covering the membrane with endothelial cells, the endothelial cells present a smooth cellular wall covering the membrane which prevents thrombosis from occurring at the membrane.

When blood pools in the left atrial appendage **13**, thrombus **30** (blood clot) can accumulate therein, build upon themselves, and propagate out from the left atrial appendage **13** into the left atrium **11** entering the blood stream, leaving the heart and can block blood flow to the heart, brain, other organs, or peripheral vessels if it becomes lodged in the arteries thereof

FIGS. **1** and **2** show a cross section of a human heart showing a thrombus **30** in the left atrial appendage **13**. The figures also show the atrial appendage ostium **20** which is to have a membrane **40** placed over it to prevent the thrombus **30** from escaping out of the atrial appendage **13** into the left atrium **11** and thus into the blood stream, which could cause a stroke, a heart attack or ischemia. The membrane **40** also prevents blood from entering the left atrial appendage **13** where it could pool due to poor circulation and become a thrombus.

FIG. **3** shows a cross section of a human heart showing a thrombus **30** in the right atrial appendage **23**. The right atrial appendage **23** can be treated in the same manner as the left atrial appendage **13**.

FIG. **4** shows a cross section of the left atrium **11**, the ostium **20** and the left atrial appendage **13** having a thrombus **30** therein.

FIG. **5** shows a first embodiment of the invention wherein the porous membrane **40** has a plurality of flexible prongs **50** which may be made from a shape memory alloy, such as Nitinol®, for retaining a predisposed shape. The prongs **50** may be atraumatic so that they do not perforate the left atrial appendage **13**. The prongs **50** may have atraumatic bulbs **55** on their tips so that the tips of the prongs **50** will not perforate the left atrial appendage **13**. Nitinol® has the property of being able to be placed in a catheter in a compact configuration and then expanded when released from the catheter to a predetermined memory shape. The shape selected may be for the prongs **50** to curve around the lip of the ostium **20** and then hug the sides of the left atrial appendage **13**. In this manner the membrane **40** will securely block the ostium **20** preventing blood from entering and particularly for preventing thrombosis **30** from leaving the left atrial appendage **13**.

The membrane **40** is self centering over the ostium **20** of the left atrial appendage **13**, by placing the prongs **50** in a circle around the membrane **40** such that the prongs **50** fit against the wall of the left atrial appendage **13** of or within the lumen of the ostium **20** to center the membrane **40** over the ostium **20**. The membrane **40** may also be centered by a centering rim **65** (see FIG. **6**) attached to the back (appendage) side of the membrane **40** that protrudes into the ostium **20** for centering. The centering rim **65** has a diameter of less than the diameter of the membrane **40**. The centering means may also consist of a series of centering cables **66** (see FIG. **11**) which attach to a spring **90** or tether **85** from the centering rim **65** or the membrane **40**, to assure that centering occurs with placement

Optionally electronics, such as sensors **300** and chips **310**, built into the membrane may be used to provide data about hemodynamics pressure, flow rates, temperature, heart rates, and electrical signals in the heart. When the membrane is placed in the left atrial appendage **13** the sensors **300** may measure pressures in the atria or atrial appendage. The sensors may also measure ventricular end diastolic pressures through the open mitral or cuspid valves. Other information about the heart may be gathered such as noise from accel-

erometers to detect leakage, valve efficiency, activity levels of the patient and other noise related data. The sensors **300** may also be blood oxygen sensors. The chip **310** may use telemetry to transmit the information gathered by the sensors **300** and processed or stored by the chip **310** to receiving devices to aid in the treatment of the patient.

In FIG. **6** the protective bulbs **55** are removed from the flexible prongs **50** of FIG. **5** such that flexible prongs **50** puncture the walls of the left atrial appendage **13** and secure the membrane **40** in place. The flexible prongs **50** may penetrate into the atrial appendage wall or extend through the atrial appendage wall. The prongs may have barbed ends **51** to prevent the prongs from withdrawing from the atrial appendage wall.

The membrane **40** has centering rim **65** attached for centering the membrane in the ostium **20** and marker **320** in the membrane **40** for observing the position of the membrane while it is being inserted. The marker may be used for x-ray or ultrasound observation.

Although Nitinol® was cited above as a type of shape memory alloy prong material which can be used, any type of memory alloy may be used. Such alloys tend to have a temperature-induced phase change which will cause the material to have a preferred configuration when heated above a certain transition temperature. Other metals which may be used as prongs include corrosion resistant spring metals such as Elgiloy® or spring tempered steel.

Another embodiment of the invention is shown in FIG. **7**. It is similar to the embodiment shown in FIG. **5**. The embodiment in FIG. **7** has a stent **60** attached to the membrane **40** for expanding in the ostium **20** helping to secure the membrane **40** thereto. The prongs **50** operate in the same manner as in FIG. **5** hugging the inner walls of the left atrial membrane **13** to secure the membrane **40** to cover the ostium **20**. The stent **60** may also be made from Nitinol®, Elgiloy® or another expandable spring loaded or balloon expandable material.

The membrane **40** may be self centering over the ostium **20** of the left **13** atrial appendage, by placing the stent **60** into the ostium wherein the stent plugs the ostium with the membrane **40** centered in the stent. Further the prongs **50** fit against the wall of the left atrial appendage **13** of or within the lumen of the ostium **20** to center the membrane **40** over the ostium **20**.

In FIG. **8** the protective bulbs **55** are removed from the flexible prongs **50** of FIG. **7** such that flexible prongs **50** puncture the walls of the left atrial appendage **13** and secure the membrane **40** in place. The flexible prongs **50** may penetrate into the atrial appendage wall or extend through the atrial appendage wall. The prongs may have barbed ends **51** to prevent the prongs from withdrawing from the atrial appendage wall.

In the embodiment shown in FIG. **9** a larger expandable stent **70** is used to both engage the sides of the ostium **20** and hug the inside walls of the left atrial membrane **13**. Again the stent may be made of Nitinol®, Elgiloy® or other material which may be delivered in a catheter and expanded to the proper size and shape to securely hold the membrane **40** over the ostium **20** to prevent blood from entering the left atrial appendage **13** and for preventing thrombosis **30** from exiting.

FIG. **10** shows another embodiment of the invention wherein the membrane **40** is secured over the ostium **20** by means of an anchor **80** which is driven into or through the wall of the left atrial appendage **13** and secured therein by the surface area of the anchor so that it will not pull out of or through the wall of the left atrial appendage **13** or cause embolism from the left atrial appendage **13**. A tether **85** is attached to the anchor **80** and to the membrane **40** to secure the membrane **40** snugly against the ostium **20**. A substance **270** such as thrombin, activated fibrinogen, or other biologic filler may be placed in the left atrial appendage **13** by injection through a catheter after the membrane **40** is in place such that blood is clotted in the atrial appendage so that it can not escape. The device delivery catheter itself may have a port for this injection. The port may also be used to inject contrast such as echocardiographic contrast that can be immediately visualized, and examined to determine whether there is a good seal between the ostium of the appendage and the device. The substance **270** injected into the atrial appendage may also be a sealant or filler to seal the membrane against leakage from the atrial appendage. The sealant material, filler material or blood clotting material may be used with any of the embodiments of the invention.

In another embodiment the catheter may inject a chemical ablation agent such as ethanol to ablate the myocardial cells in the sealed off atrial appendage **13** and thus limit atrial fibrillation by limiting or eliminating electrical propagation in the atrial appendage.

FIG. **11** shows another embodiment of the invention wherein membrane **40** has a spiral spring **90** in addition to the anchor **80**. The spiral spring **90** can be used in conjunction with or separately from the tether **85** to pull the membrane **40** against the ostium **20**. Although a spiral spring **90** has been shown in FIG. **11** the shape used may be oval, cylindrical, oblong, or other shape to connect the anchor **80** to the membrane **40**. In another embodiment shown in FIG. **12** the spiral spring **90** may fill the volume of the left atrial appendage **13** securing the membrane **40** to the ostium **20**. The spiral spring **90** filling the left atrial appendage **13** may also have an anchor **80** and tether **85** to help secure the membrane **40** to the ostium **20**. Alternatively centering rim **65** may be used as shown in FIG. **11** to center the membrane **40** over ostium **20** of left atrial appendage **13**. Centering cables **66** connected to spring **90** and either membrane **40** or centering rim **65** may also be used to center the membrane **40** over the ostium **20**.

FIG. **13** shows yet another means of securing the membrane **40** over the ostium **20**. In this embodiment membrane **40** is directly attached to the ostium **20** by an adhesive **100**.

FIG. **14** shows a delivery catheter **125** containing a collapsed porous membrane **40** and a collapsed disk **130** connected to the porous membrane **40** by a spring **90** on catheter **21**. The disk **130** may be made of a flexible woven metal or a flexible woven metal with a thin porous polymer sandwiched inside. Disk **130** may also be a polymer weave. The disk **130** is flexible and compresses or folds so it fits into the delivery catheter **125** and expands to its desired shape after release from the delivery catheter **125**. Similarly membrane **40** compresses or folds to fit into the delivery catheter **125** and expands to its desired shape after release. FIG. **15** shows the porous membrane **40**, disk **130** and spring **90** from FIG. **14** in an expanded configuration outside of the delivery catheter **125**.

FIG. **15** shows the spring **90** connecting the porous membrane **40** and the disk **130** for urging them together. In other embodiments an elastic tether or a tether with teeth and a pawl on the porous membrane **40** to form a ratchet can also be used to pull the porous membrane **40** and the disk **130** together.

FIG. **16** shows the device of FIG. **15** applied to the left atrial appendage **13** having thrombus **30**. After the device is

applied the spring **90**, pulls the disk **130** toward the porous membrane **40** collapsing the left atrial appendage **13** and trapping the thrombus **30** therein as shown in FIG. **17**.

FIG. **18** shows an alternate embodiment of the device in FIGS. **16** and **17** wherein the catheter **21** is equipped with a vacuum **140** for sucking out blood and thrombosis **30** found in the left atrial appendage **13**. The vacuum **140** will help collapse the left atrial appendage **13** such that spring **90** need not be as large as in FIG. **16**.

FIG. **19** shows an alternative embodiment of the device where the membrane **150** is inserted into the left atrial appendage **13** and fills it securing the membrane **150** therein. The membrane **150** may be delivered in a catheter as a compressed material and expanded in the atrial appendage **13** or be delivered in a liquid form which will fill the atrial appendage and be transformed into a membrane by curing with another chemical delivered by the catheter or with the aid of a UV light supplied through a fiber optic cable in the catheter **21**. By filling the left atrial appendage **13** with a membrane material **150** no blood can enter to pool and become a thrombus **30** and no thrombus **30** can exit to cause heart attacks, strokes and ischemia.

FIGS. **20–22** show another embodiment of the invention using an umbrella principle for securing the membrane **40** against the ostium **20**. FIG. **17** shows closed umbrella struts **160** entering the ostium **20** of left atrial appendage **13**. The membrane **40** is some distance back from the umbrella struts **160** at the bottom of the range of teeth **195** on pole **170**. FIG. **21** shows the umbrella struts inside of the left atrial appendage **13** with the struts **160** open. Umbrella opening structure **175** on pole **170** pushes the struts out to the umbrella open position. The umbrella opening structure **175** can be pushed to the open position or have a spring loaded mechanism to push the struts **160** to the open position. The ends of the umbrella struts **160** engage the left atrial appendage wall around the ostium **20** and prevent the umbrella from being withdrawn from the left atrial appendage **13**. The ends of the umbrella struts **160** that engage the atrial appendage wall may be blunted or have bulbs on the tips or have padding so as not to puncture the left atrial appendage **13**. FIG. **22** shows the membrane **40** drawn up against the ostium **20** by ratcheting the membrane along pole **170**. The pawl mechanism **200** engages teeth **195** on pole **170** and is moved forward to snugly block the ostium **20** with the membrane **40**.

FIG. **23** shows a stent **260** applied to the ostium **20** of left atrial appendage **13**. The stent **260** expands after leaving a delivery catheter such that the wall of the stent secures the stent by pressure to the ostium **20**. Membrane **240** folds or is compressed into the delivery catheter and expands as the stent **260** expands and lodges in the ostium **20** of the left atrial appendage **13**.

FIG. **24** shows the left atrial appendage **13** compressed such that the volume of the atrial appendage is reduced to almost nothing. With the volume reduced the atrial appendage will not have a large volume of blood which can produce a thrombus. In the embodiment shown disk **130** and spring **90** pull the left atrial appendage **13** toward membrane **40**. Although FIG. **24** shows the use of a disk **130** and spring **90** to act on the left appendage any method to reduce the volume of the atrial appendage as much as possible may be used. In addition to physically reducing the volume a substance **270** may be injected into the appendage to further limit its volume, or to clot the blood already present therein.

As shown in FIG. **24** the membrane **40** is much larger than the ostium **20**. The over-size membrane **40** may be used in all embodiments to ensure that the ostium **20** is completely blocked.

The devices described above may be percutaneously delivered to the left and right atrial appendages **13, 23** respectively. The devices may have materials in them which enhance visualization or imaging by ultrasound, x-ray or other means making it easier for the device to be implanted and accurately centered over the ostium **20** of the atrial appendage **13**. This may consist of small beads placed strategically on the membrane, the connecting elements, or on the anchors. Referring to FIG. **1** catheter **21** is seen entering the heart by way of the aorta **12** to the left ventricle **16** passing through the mitral valve **17** and then entering the left atrial appendage **13** to apply the porous membrane **40** in one of the embodiments as disclosed above. In FIG. **2** the catheter **21** enters the heart from the femoral vein, passes through the inferior vena cava **18** to the right atrium and then passes through the fossa ovalis **19** or through the septum **29** into the left atrium **11** and then approaches the left atrial appendage **13** to apply the porous membrane **40** thereto. FIG. **3** shows the catheter **21** being applied to the right atrial appendage **23**. Catheter **21** may enter the heart through the jugular vein **28** or the femoral vein to the inferior vena cava **18**.

It should be understood that the invention may be practiced with numerous means of attaching the membrane **40** to cover the ostium **20** of the atrial appendages **13** and **23**. Any combination of the attachment means with adhesives, prongs, stents, anchors, disks, tethers or springs may be used. The membrane may also be inside of the atrial appendages **13** and **23**, or may penetrate the atrial appendage and provide a means to securely lock the membrane device into place. Other means of providing a membrane for blocking blood flow into and blood clots out of the atrial appendages not listed may also be used. A substance may be injected into the appendage to limit its volume, or to clot the blood already present.

In all of the above embodiments the blood of the appendage may be facilitated to clot in order to form a large, immobile mass. Alternatively, the appendage may be filled with any substance that will occupy volume. Examples are fibrin, prosthetic polymers (PLLA), Silicone, or a balloon that is delivered and remains in place for long periods of time.

All of the above embodiments shown and discussed for the left atrial appendage **13** are also useable on the right atrial appendage **23**. Further the invention may be used to close fistulae or connections elsewhere in the body such as the colon or bronchopulmonary systems. The invention may also be used to seal false aneurysms. When the membrane is placed in a false aneurysm it will strengthen the defect and may help to avoid surgery.

Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

What is claimed is:

1. A method of preventing atrial appendage thrombus from entering the blood stream comprising:

securing a membrane over an ostium of the atrial appendage by extending prongs from adjacent an edge of the membrane into the atrial appendage through the ostium; and

piercing the wall of the atrial appendage with the prongs extending into the atrial appendage wall substantially adjacent the ostium to secure the membrane in place; thereby:

blocking the atrial appendage ostium with the membrane preventing blood from entering the atrial appendage and forming thrombus therein and preventing thrombus formed therein from leaving.

2. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

centering the membrane over the ostium by attaching the prongs adjacent the edge of the membrane substantially in a circle such that the prongs will position the membrane over the ostium without leaving gaps between the ostium and the membrane.

3. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

extending a stent between the membrane and the prongs to engage the ostium of the atrial appendage for securing the membrane to the ostium.

4. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

securing the membrane over the ostium of the atrial appendage by extending stent legs into the atrial appendage through the ostium of the atrial appendage to hold the membrane snugly against the ostium of the atrial appendage.

5. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

attaching the membrane to the ostium of the atrial appendage by extending a collapsible stent into the ostium such that the stent expands and engages the circumference of the ostium and attaching a collapsible membrane across the lumen of the stent such that opening the stent stretches the membrane across the lumen of the stent thus blocking the ostium.

6. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

coating the membrane with an anticoagulant drug to prevent thrombosis.

7. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

providing a porous membrane for encouraging endothelial cells to grow in the membrane thus providing a cell wall over the membrane to prevent thrombosis.

8. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

injecting a blood coagulating substance into the atrial appendage to clot the blood therein and prevent it from flowing out of the atrial appendage.

9. A method of preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

injecting an ablative chemical into the atrial appendage to ablate myocardial tissue thus preventing electrical propagation of atrial fibrillation.

10. A method for preventing atrial appendage thrombus from entering the blood stream as in claim 1 further comprising:

providing a means for centering the membrane over the ostium of the atrial appendage to provide a good seal.

11. A method of obstructing an opening in the body of a patient, said method comprising:

minimally invasively inserting a membrane in the opening by use of a catheter to block the opening; and

securing the membrane in place by the membrane lodging against the opening and providing prongs adjacent an edge of the membrane extending substantially outwardly for attaching the membrane to body tissue on the opposite side of the opening substantially adjacent the opening.

12. A method of obstructing an opening in the body of a patient as in claim 11 wherein the securing comprises:

securing the membrane over a false aneurysm.

13. A method of obstructing an opening in the body of a patient as in claim 11 wherein the securing comprises:

securing the membrane over a fistula.

14. A method of obstructing an opening in the body of a patient as in claim 11 wherein the securing comprises:

securing the membrane over an ostium of an atrial appendage.

15. A method of preventing thrombus in the atrial appendage of a patient from entering the blood stream, said method comprising:

providing a filter membrane between the atrial appendage and the atrium;

securing the filter membrane over an ostium of the atrial appendage by extending engagement members substantially outwardly from adjacent an edge of the filter membrane into the atrial appendage through the ostium of the atrial appendage; and

piercing the wall of the atrial appendage with the engagement members extending into the atrial appendage wall substantially adjacent the ostium to secure the filter membrane in place; thereby:

filtering blood flow to prevent thrombus from flowing out of the atrial appendage.

16. The method as defined in claim 15, wherein the plurality of engagement members is attached adjacent the edge of the filter membrane in a substantially circular configuration, the method further comprising:

centering the filter membrane over the ostium by the engagement members positioning the filter membrane relative to the ostium.

17. The method as defined in claim 15, further comprising:

expanding a cylindrical support member to which the filter membrane and the engagement members are attached, to engage the ostium of the atrial appendage for securing the filter membrane across the ostium.

18. The method as defined in claim 15, further comprising:

attaching the filter membrane and the engagement members to a portion of a collapsible structure;

attaching the filter membrane to the ostium of the atrial appendage by extending the collapsible structure into the ostium and expanding the collapsible structure; such that:

the collapsible structure expands and engages the circumference of the ostium; and

the filter membrane is stretched across the ostium.

19. The method as defined in claim 15, further comprising:

coating the filter membrane with an anticoagulant drug to prevent thrombosis.

20. The method as defined in claim 15, wherein the filter membrane is structured to encourage endothelial cells to grow in the filter membrane thus providing a cell wall over the filter membrane to prevent thrombosis.

21. The method as defined in claim 15, further comprising:

providing a means for centering the filter membrane over the ostium of the atrial appendage to provide a good seal.

22. A method of preventing atrial appendage thrombus from entering the blood stream comprising:

blocking an atrial appendage ostium with a membrane preventing blood from entering the atrial appendage and forming thrombus therein and preventing thrombus formed therein from leaving; and

injecting a blood coagulating substance into the atrial appendage to clot blood therein and prevent blood from flowing out of the atrial appendage.

* * * * *

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(12) **United States Patent**
Hahnen

(10) **Patent No.: US 6,270,490 B1**
(45) **Date of Patent: *Aug. 7, 2001**

(54) **VENOUS DRAINAGE CATHETER AND METHOD OF USE**

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(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(52) **U.S. Cl.** **604/509**; 604/104; 604/164.03; 604/105; 606/191; 606/194; 606/198

(58) **Field of Search** 604/27, 53, 43, 604/19, 28, 48, 500, 73, 93, 173, 264, 523, 164.01–164.03, 509; 606/189, 104, 105

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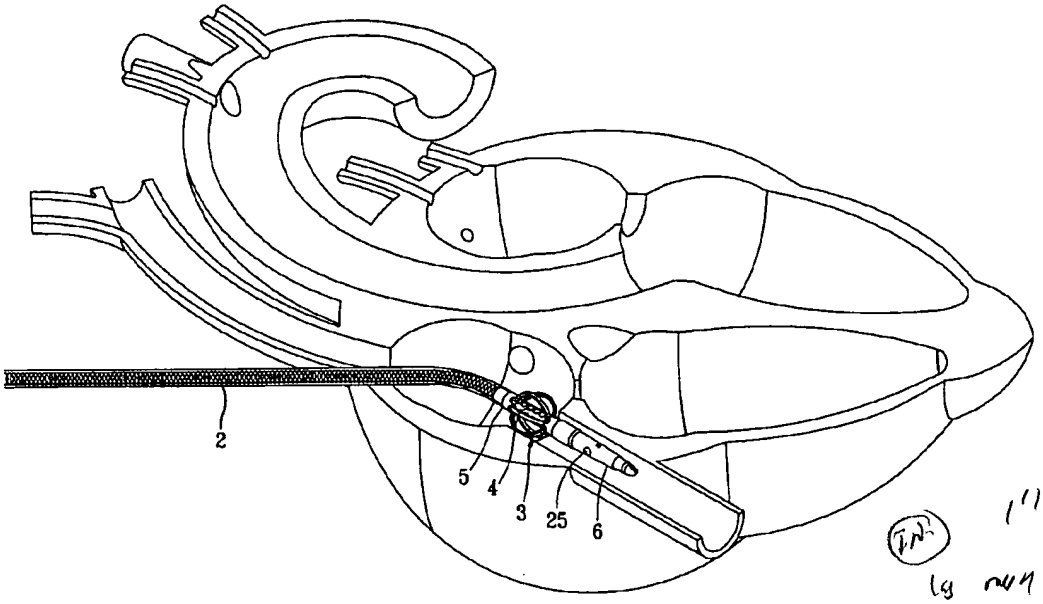
(57) **ABSTRACT**

A venous drainage catheter comprising a cannula and a lumen, wherein the proximal end is adapted for attachment to a bypass machine and the distal end has a drainage port in fluid communication with the cannula lumen. Expanding members, having an actuating mechanism which expand the members from a collapsed condition, are disposed circumferentially about the drainage port. Methods for using the devices are also disclosed.

4 Claims, 9 Drawing Sheets



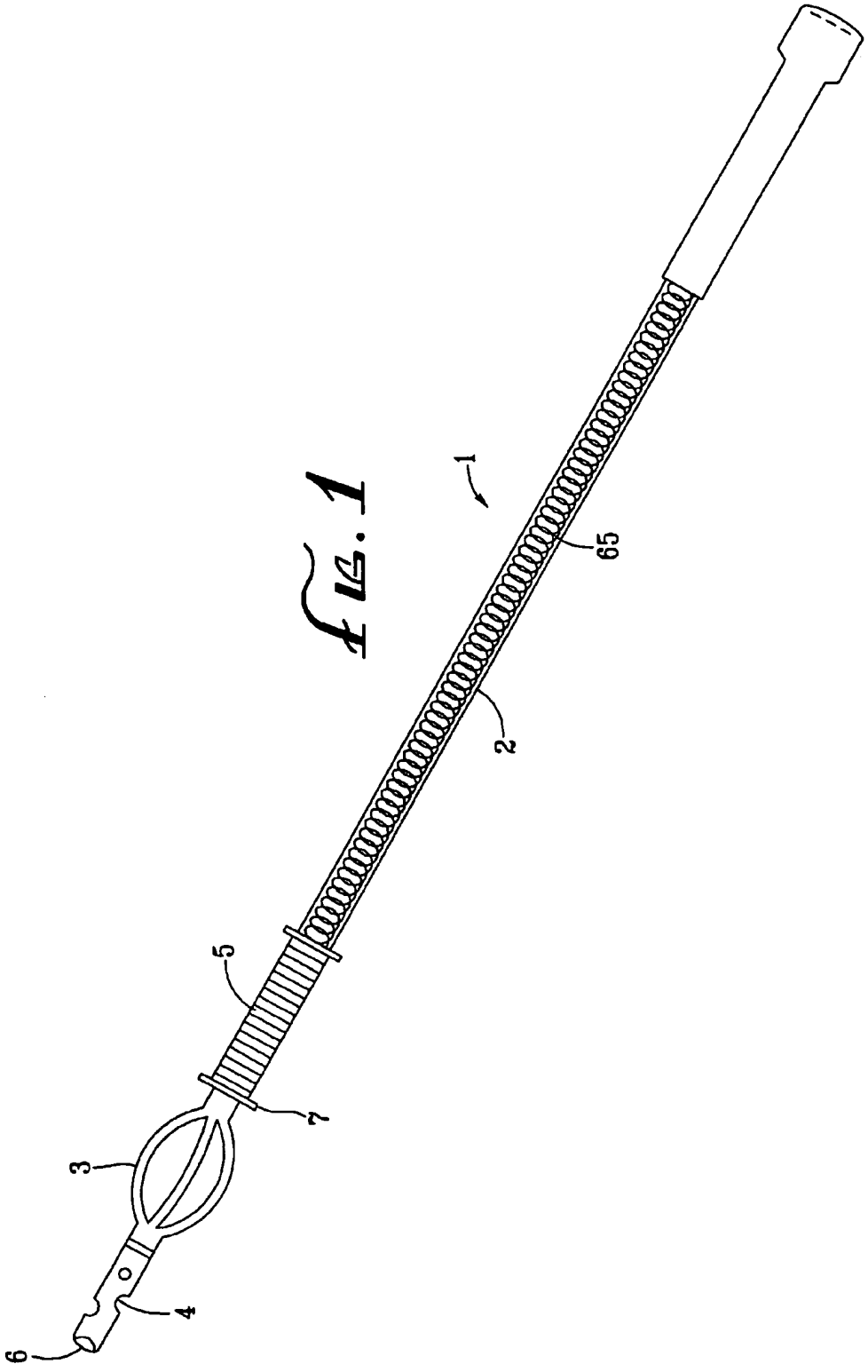


Fig. 1

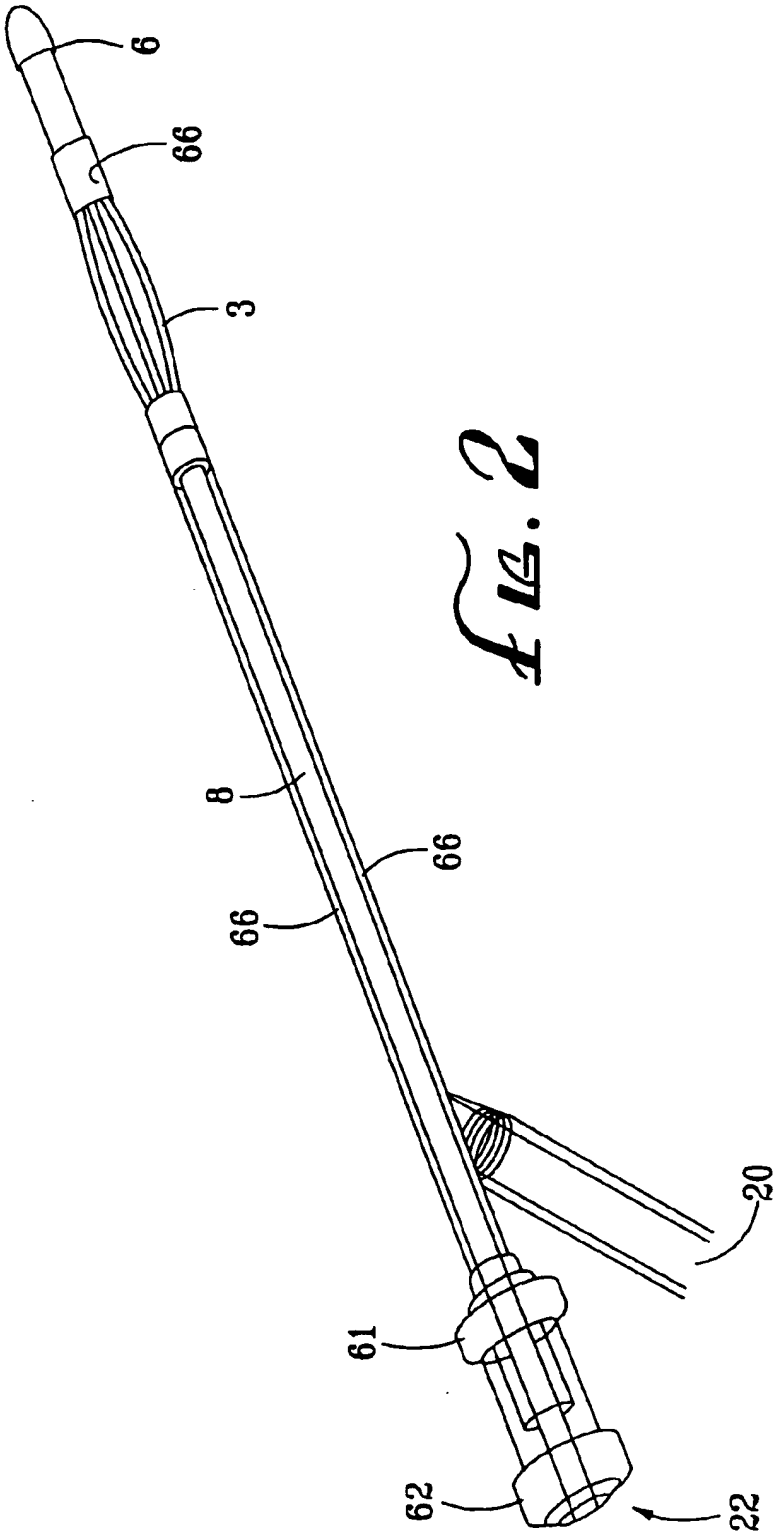


FIG. 2

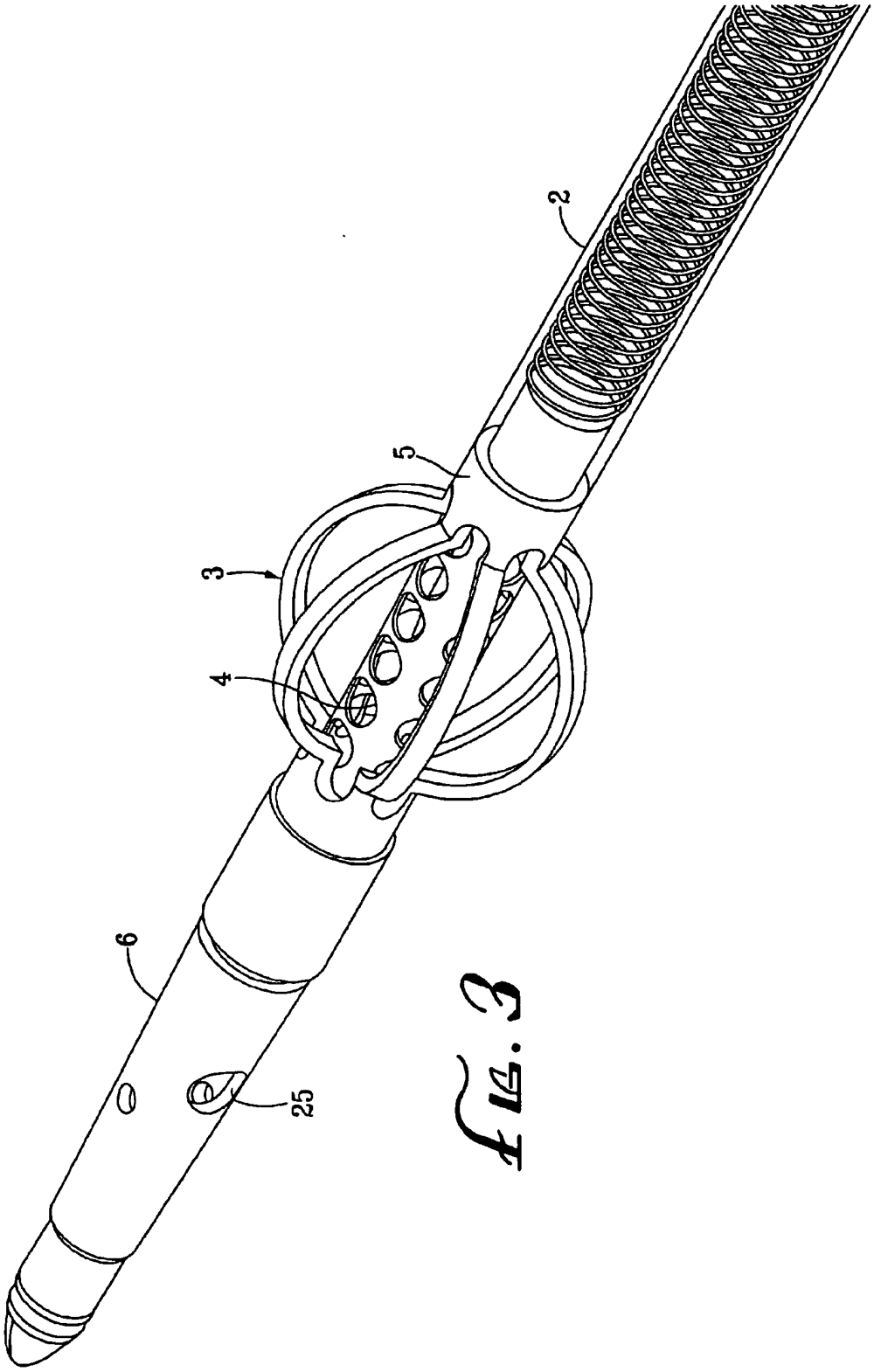
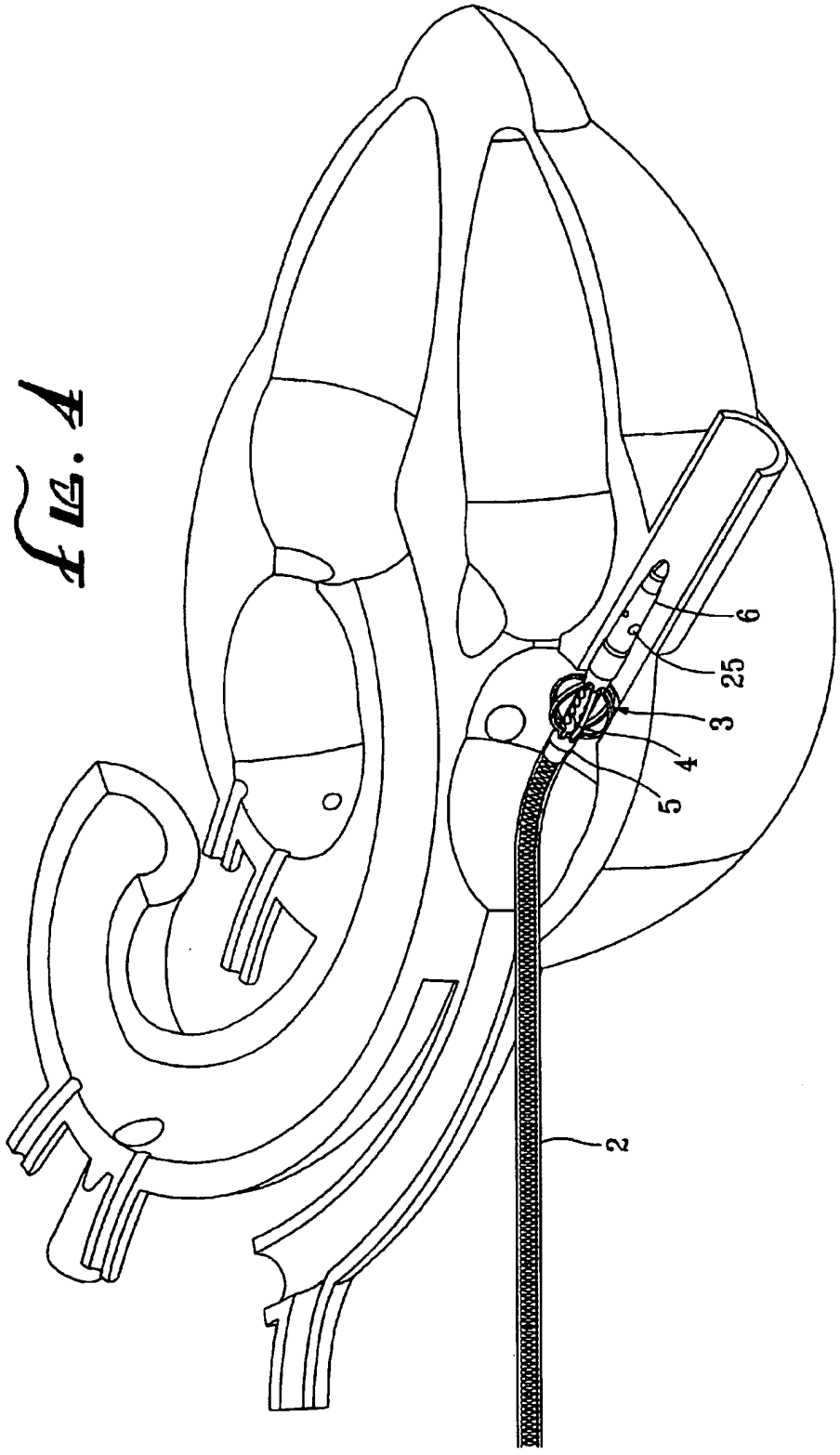


Fig. 3

FIG. 4



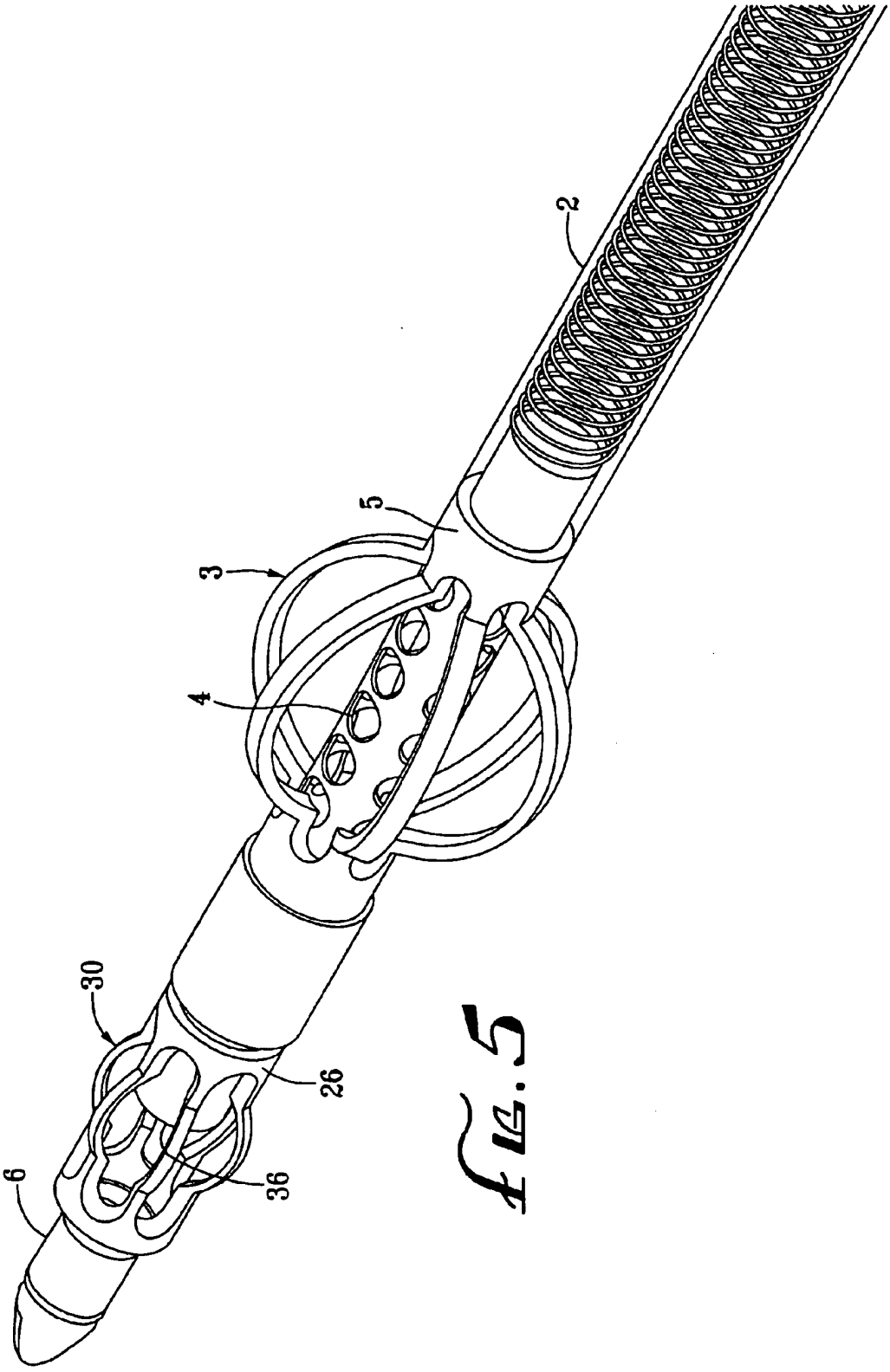
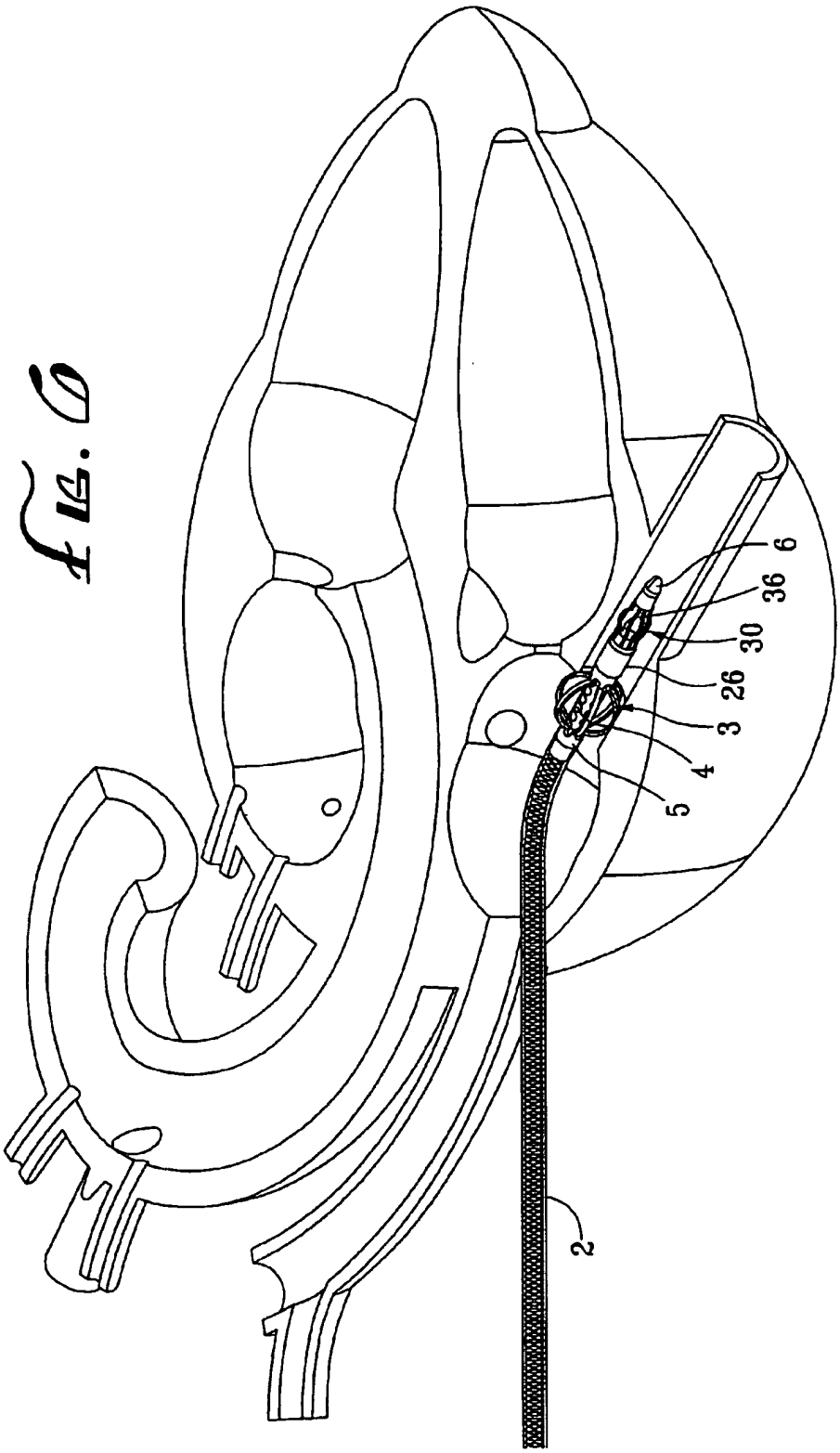


FIG. 5

FIG. 6



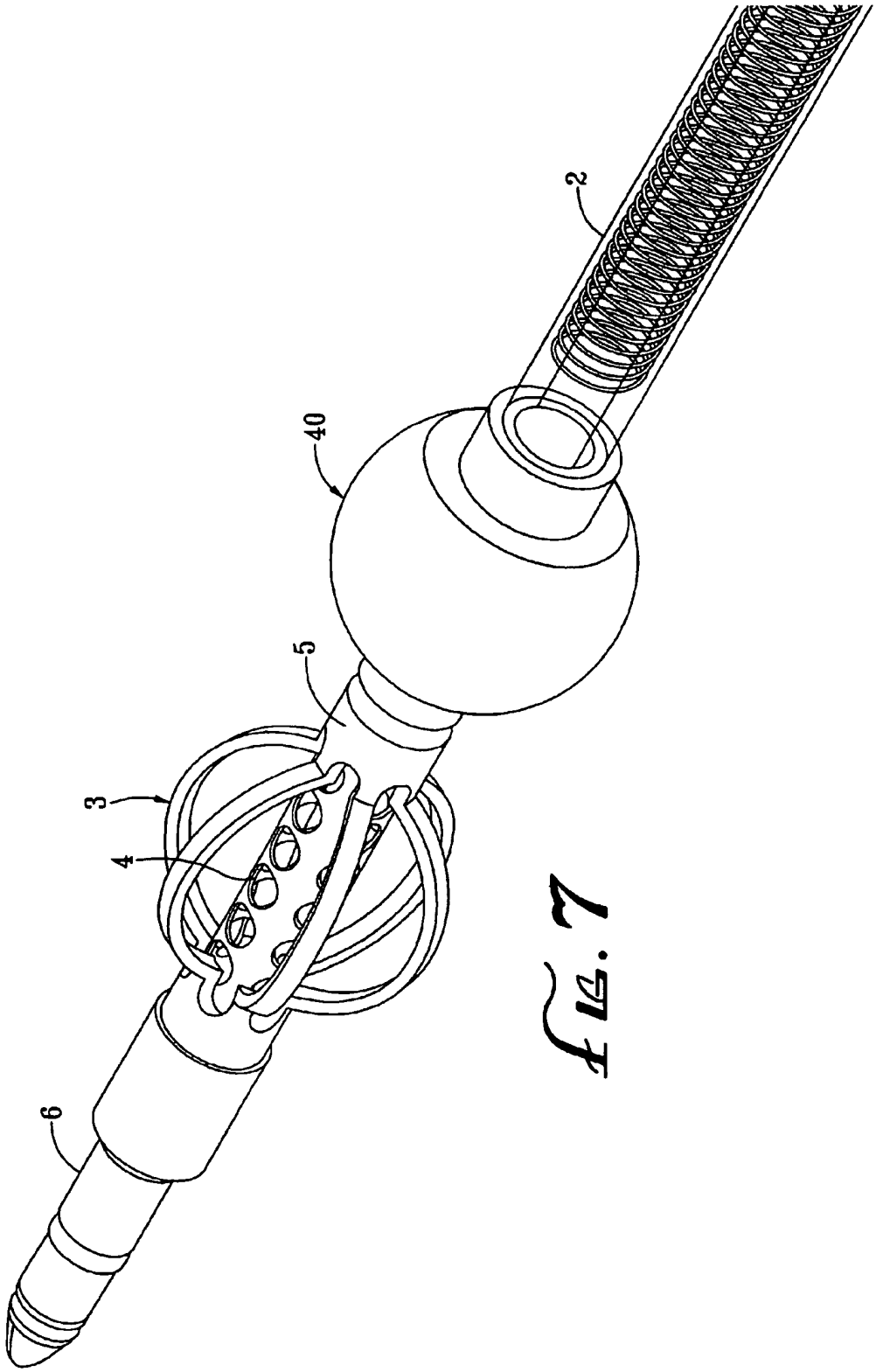


FIG. 7

Fig. 8

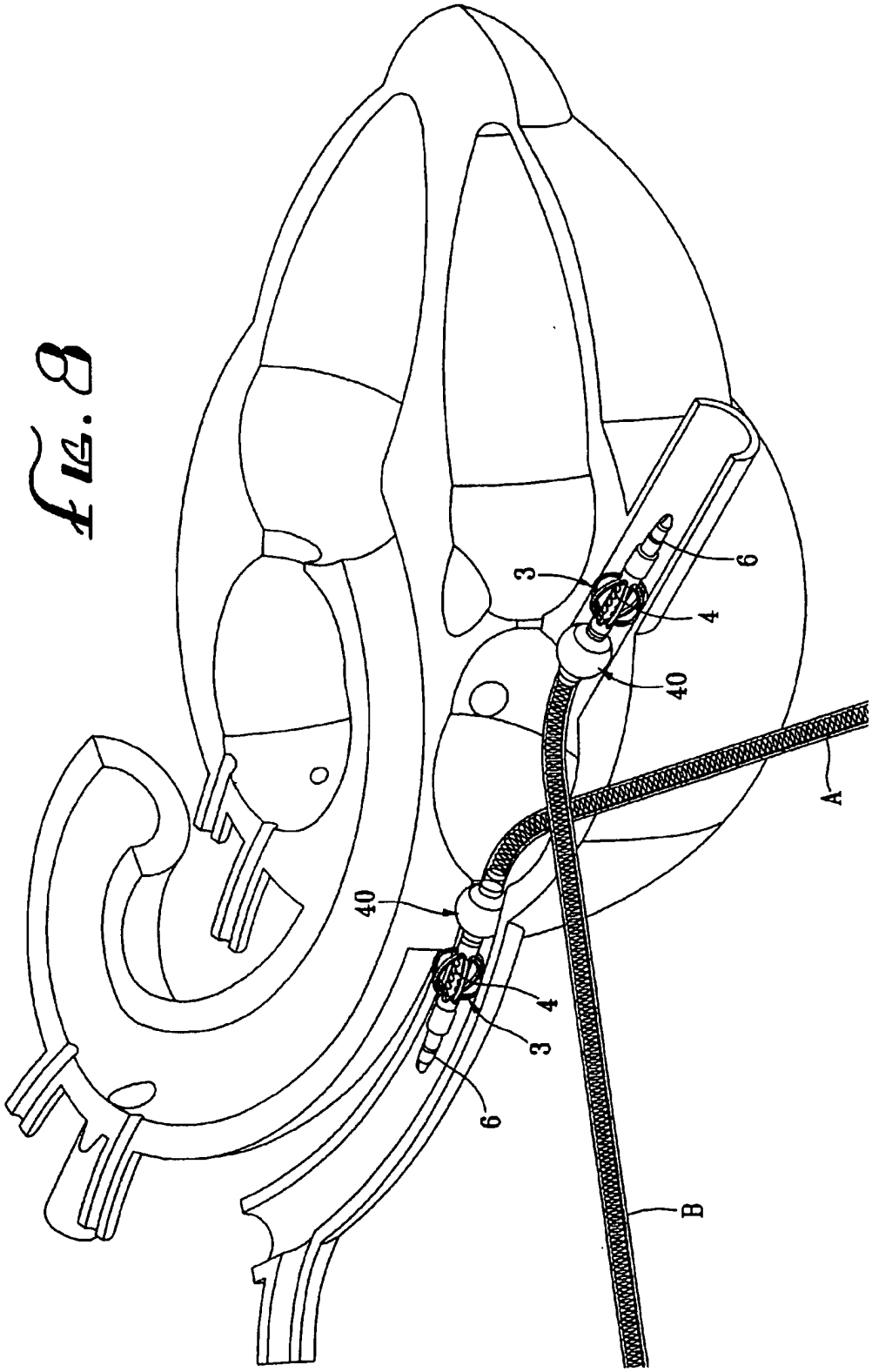
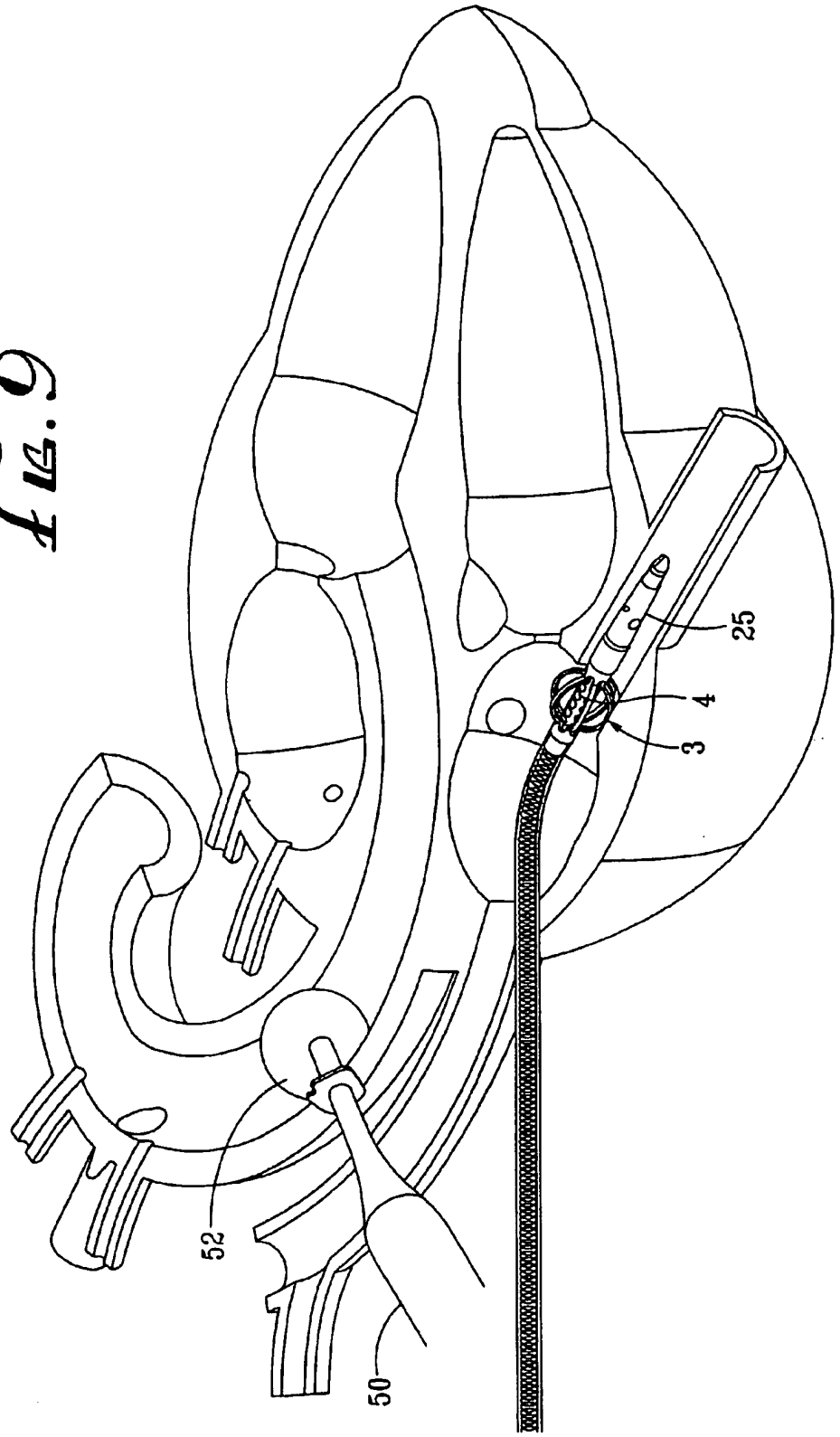


Fig. 9



VENOUS DRAINAGE CATHETER AND METHOD OF USE

FIELD OF THE INVENTION

The present invention relates to a venous drainage catheter for drainage of blood from the right atrium, inferior vena cava, or superior vena cava during cardiopulmonary bypass. More particularly, the invention relates to a venous drainage catheter comprising a cannula and expanding members disposed circumferentially about drainage ports for maintaining fluid access to the drainage ports.

BACKGROUND OF THE INVENTION

Cardiopulmonary bypass is commonly used to maintain oxygen delivery to peripheral organs during cardiopulmonary arrest in a variety of cardiothoracic surgeries, septal defect repairs, heart valve repairs and replacement, aneurysm repairs, and corrections of congenital defects. Before cardiopulmonary bypass can be initiated, the heart and coronary blood vessels must be isolated from the peripheral vascular system. This is usually accomplished by arterial cannulation of the aorta and venous cannulation of the right atrium, inferior vena cava, or superior vena cava. Venous drainage catheters are commonly used to withdraw the deoxygenated blood from the right atrium, inferior vena cava, or superior vena cava, pass it to a bypass oxygenator machine, and the blood is thereafter returned to the patient's aorta.

Venous drainage catheters typically include at least one drainage port at the distal end. However, the walls of the organ or vessel within which the drainage ports are disposed will often close down around the drainage ports and thereby obstruct the flow of blood into the cannula. This difficulty will often prevent adequate drainage of blood to the bypass oxygenator machine. Thus, a need exists for an improved venous drainage catheter to prevent obstruction of drainage ports by adjacent tissues during operation.

SUMMARY OF THE INVENTION

The present invention solves these and other problems by providing a venous drainage catheter comprising a cannula having drainage ports at its distal end, and expanding members disposed about the drainage ports. The expanding members serve to keep the organ walls from closing down around the cannula drainage ports. This result is accomplished by providing a larger surface area in the target vessel or organ than is obtainable from conventional catheters or cannulae. This feature promotes flow into the targeted site. This feature of providing a larger surface area also helps to create a venturi effect to facilitate drainage. The expanding members may comprise ribs, fins, mesh, or arms, and generally are embodied as bellows. By use of the present invention, the incision site or the access into the organ is substantially smaller than the expanded diameter of the expanding members.

The present invention relates to a venous drainage catheter comprising a cannula, expanding members, and an actuating mechanism for operating the expanding members. The cannula will generally have a proximal end, a distal end, and a lumen therebetween, the proximal end being shaped for attachment to a bypass oxygenator machine. The distal end will typically include at least one drainage port, or more preferably, a plurality of drainage ports comprising two drainage ports, more preferably three drainage ports, more preferably four drainage ports, more preferably five drainage ports, or more. The drainage ports are in fluid communication with the lumen of the cannula.

The expanding members can be any of ribs, fins, mesh, arms, or bellows. The expanding members are disposed circumferentially about the drainage ports, and may be mounted on the cannula or carried by some other member. The expanding members are capable of expanding from a collapsed condition to a radially expanded condition.

The actuating mechanism for operating the expanding members may include any mechanism that allows deployment of the expanding members by operation from a location proximal the expanding members on the cannula. As but one example of an actuating mechanism, the invention provides a cylindrical sheath disposed circumferentially about the expanding members to maintain the expanding members in a collapsed condition. The sheath is slidable proximally to release the expanding members, where upon the expanding members expand radially outwardly. In certain embodiments of the invention, the sheath will further include a rib mounted at its proximal edge, the rib shaped to engage an incision during use. The rib provides an anchor to stabilize the sheath during advancement of the cannula distally, and may also provide a hemostatic seal to prevent blood loss during use of the venous drainage catheter.

The invention also provides a tubular housing for use in a venous drainage catheter system. The tubular housing includes a proximal end, a distal end, and a lumen therebetween. The lumen is shaped to receive the blood cannula. At a proximal end of the housing, a side opening is provided which communicates with the lumen of the housing and is shaped to allow passage of the cannula through the side opening. The distal end of the housing may have an opening positioned to align longitudinally with the drainage port of the cannula. The expanding members may be disposed circumferentially about the one or more distal openings on the housing, and the expanding members may be mounted on the tubular housing.

The invention also provides methods for draining venous blood from the right atrium of a patient. The surgeon provides a venous drainage catheter as described herein. The surgeon makes an incision in the patient to provide access to the atrial appendage. The cannula, or housing, is inserted through the incision and into the right atrium. The expanding members are activated to the expanded condition to hold tissue away from the drainage port. When a housing is used, the drainage cannula is inserted through the proximal opening of the housing and advanced distally into the atrium. The drainage ports are aligned with a distal opening on the housing. In both methods, the proximal end of the cannula is then attached to a bypass oxygenator machine. Venous blood is then withdrawn from the right atrium and is oxygenated before return to the patient's arterial circulation.

According to the invention, the atrial appendage may be sealed circumferentially about the venous drainage catheter by use of a purse-string suture. In another method, the venous drainage catheter includes the cylindrical sheath disposed about and covering the expanding members to maintain them in a collapsed condition. During use, the cylindrical sheath engages the incision, and is held stable while the cannula is advanced distally, thereby sliding beyond the sheath. By sliding the cannula distally, the expanding members are released inside the right atrium and thereby expand to an expanded condition.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference is now made to a brief description of the drawings, which are intended to illustrate a venous drainage

catheter for use herein. The drawings and detailed description which follow are intended to be merely illustrative and are not intended to limit the scope of the invention as set forth in the appended claims.

FIG. **1** depicts a longitudinal view of a venous drainage catheter.

FIG. **2** depicts an alternative embodiment of a venous drainage catheter having arcuate handles at its proximal end.

FIG. **3** depicts another alternative embodiment of a venous drainage catheter.

FIG. **4** depicts the venous drainage catheter of FIG. **3** deployed in the right atrium.

FIG. **5** depicts a venous drainage catheter having two expanding members at its distal end.

FIG. **6** depicts the venous drainage catheter of FIG. **5** deployed in the right atrium.

FIG. **7** depicts a venous drainage catheter having an expandable balloon at its distal region.

FIG. **8** depicts two venous drainage catheters of FIG. **7** deployed in the right atrium.

FIG. **9** depicts a venous drainage catheter deployed in the right atrium and an arterial cannula deployed in the aorta.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A first embodiment of a venous drainage catheter is depicted in FIG. **1**. Venous drainage catheter **1** is generally an elongated cylindrical element comprising cannula **2** having a proximal end, a distal end **6**, and a lumen therebetween. Cannula **2** includes a plurality of drainage ports **4** disposed at the distal end of cannula **2**. In certain embodiments, a single port will be adequate to withdraw blood at a sufficient rate for bypass. In other embodiments, two, three, four, five, or more ports may be necessary to accomplish cardiopulmonary bypass. The catheter may also include coil **65** to prevent kinking of the cannula, which may impede blood flow. Bellows **3** are arranged circumferentially proximal drainage ports **4**, and provide fluid access to the cannula lumen. Cylindrical sheath **5** is disposed slidingly about cannula **2**, sheath **5** further comprising a circumferential rib **7** in certain embodiments. Sheath **5** can be positioned to surround bellows **3**, thereby radially compressing the bellows before deployment.

In use, the cannula shown in FIG. **1** is provided with sheath **5** disposed over bellows **3**. An incision is made in the patient to provide access to the atrial appendage, typically by an intercostal route. Distal end **6** of cannula **2** is advanced through the incision and into the right atrium through the atrial appendage. As sheath **5** engages the incision at circumferential rib **7**, cannula **2** is slid distally through sheath **5**. Bellows **3** advances distally beyond sheath **5**, thereby releasing the bellows as they enter the right atrium. Bellows **3** serves to maintain tissue in the right atrium spaced from drainage ports **4** sufficiently to provide unimpeded fluid access to drainage ports **4** and to the cannula lumen between the bellows. Expanding members **3** are thereby automatically actuated upon entry into the right atrium. The proximal end of cannula **2** is then attached to a bypass oxygenator machine and blood is withdrawn from the right atrium.

In another embodiment, a venous drainage catheter is provided as depicted in FIG. **2**. The catheter includes distal end **6**, proximal end **22**, and lumen **8**. Distal end **6** includes at least one drainage port in fluid communication with lumen **8** of the catheter. An expanding member, shown here as bellows **3**, may be disposed circumferentially about the drainage ports. Proximal end **22** includes arcuate handles **61** and **62**, which are slidable relative to one another. Handle **61** may be joined to distal end **6** by one or more wires **66**, while handle **62** is mounted to the proximal end of the catheter. Handle **61** and **62** are compressed during operation to retract distal end **6**, thereby causing bellows **3** to expand radially outward. The proximal end of the catheter may also include a locking mechanism to lock handles **61** and **62** at a fixed displacement during use. The proximal end of the catheter further includes side port **20** which is adapted for attachment at its proximal end to a bypass-oxygenator machine. The lumen of port **20** merges and communicates distally with lumen **8** of the catheter, which lumen receives blood from the distal drainage port.

In use, the catheter has bellows **3** in a collapsed condition. An incision is made in the patient to provide access to the atrial appendage. Distal end **6** is inserted through the incision and into the right atrium. Handles **61** and **62** are compressed, thereby expanding bellows **3** radially outward to maintain tissue away from the drainage port and maintain fluid access to the drainage port. Deoxygenated blood is delivered from the right atrium through the drainage port and lumen **8** to a bypass-oxygenator machine through port **20**.

In another alternative embodiment depicted in FIG. **3**, expanding members **3**, shown here as bellows, are arranged circumferentially about drainage ports **4** of cannula **2**. Cannula **2** further includes drainage port **25** at distal end **6**. A cylindrical sheath (not shown) may be disposed slidably about cannula **2** to surround expanding members **3**, thereby compressing the expanding member before deployment.

The venous drainage catheter of FIG. **3** is shown entering and deployed in the right atrium in FIG. **4**. After an incision is made on the atrial appendage, distal end **6** of cannula **2** is advanced through the incision and into the right atrium, and expanding members **3** are decompressed and engaged in the opening of the inferior vena cava to the right atrium, holding atrial tissue away from drainage ports **4**. Deoxygenated blood from the inferior vena cava and the right atrium can then enter through port **25** and ports **4**, respectively, and be delivered to a bypass oxygenator machine.

FIG. **5** depicts another embodiment of a venous drainage catheter having two expanding members. Cannula **2** has drainage port **36** at distal end **6** in addition to drainage ports **4**. Expanding members **3** and **30**, shown here as bellows, surround drainage ports **4** and drainage port **36**, respectively. Cylindrical sheaths (not shown) may be disposed slidably about cannula **2**. Such sheaths surround expanding members **3** and **36**, thereby radially compressing both expanding members before deployment.

In FIG. **6**, the venous drainage catheter of FIG. **5** is shown deployed in the right atrium. After an incision is made in the right atrial appendage by an access mechanism, the venous drainage catheter is inserted through the incision into the right atrium. A sheath (not shown) engages the incision, and cannula **2** is slid distally through the sheath, thereby releasing expanding member **3** by advancing the expanding members distally beyond the sheath. Distal end **6** of the venous drainage catheter is advanced into the inferior vena cava until expanding members **3** engage the opening of the inferior vena cava to the right atrium. In this way, expanding members **3** facilitate flow of the deoxygenated blood through drainage ports **4** from the right atrium, whereas expanding members **30** facilitate flow of deoxygenated blood through drainage port **36** from the inferior vena cava by keeping vascular tissue from collapsing on the drainage ports.

In FIG. **7**, another alternative embodiment of a venous drainage catheter is shown having expandable balloon **40** mounted proximal to bellows **3**. Drainage ports **4** again are surrounded by expanding members **3**, shown here as bellows. A cylindrical sheath (not shown) may be disposed slidably about cannula **2** engaging bellows **3** before deployment. Expandable balloon **40** is sized to engage the openings of the inferior vena cava or superior vena cava into the right atrium.

In FIG. **8**, two venous drainage catheters are shown deployed within the right atrium. After an incision is made in the right atrial appendage, venous catheter A and venous catheter B are inserted through the incision into the right atrium. Expanding members **3** are released and expandable balloons **40** are inflated on both catheters. Catheter A is advanced in a cephalad direction to engage balloon **40** at the opening of superior vena cava into the right atrium. Catheter B is advanced in a caudal direction to engage balloon **40** at the opening of the inferior vena cava in to the right atrium. The balloons provide a seal at the atrial inlet, and thus facilitate venous drainage in the inferior vena cava and superior vena cava by minimizing runoff of deoxygenated blood into the right atrium. The expanding members further improve venous drainage by keeping the drainage ports open.

Arterial and venous cannulation are both required to initiate CPB. In FIG. **9**, a venous drainage catheter **1** is deployed in the right atrial cannula whereas an arterial cannula **50** is deployed in the ascending aorta. Arterial cannula **50** includes expandable balloon **52** for occluding the aortic lumen. Venous drainage catheter **1** includes expandable member **3** (shown here as ribs) surrounding drainage ports **4** to prevent collapse of atrial tissue around the drainage ports. The venous drainage catheter drains venous blood from the inferior vena cava through port **25** and from the right atrium through ports **4**, and delivers deoxygenated blood to an oxygenator bypass machine. The bypass machine then returns oxygenated blood to the ascending aorta through arterial cannula **50**, thereby providing circulatory isolation of the heart and coronary blood vessels from the peripheral vascular system.

While particular devices and methods have been described for venous drainage catheters, once this description is known, it will be apparent to those of ordinary skill in the art that other embodiments and alternative steps are also possible without departing from the spirit and scope of the invention. Moreover, it will be apparent that certain features of each embodiment as well as features disclosed in each reference incorporated herein can be used in combination with devices illustrated in other embodiments. Accordingly, the above description should be construed as illustrative, and not in a limiting sense, the scope of the invention being defined by the following claims.

What is claimed is:

1. A method for draining venous blood from the right atrium of a patient, comprising the steps of:

providing a venous drainage catheter comprising a cannula having a drainage port at a distal end thereof, the drainage port in fluid communication with a lumen of the cannula, the cannula further having expanding members disposed about said drainage port and a cylindrical sheath disposed circumferentially about the expanding members;

making an incision in an atrial appendage of the patient to provide access to the right atrium;

inserting the cannula through the incision and into the right atrium, wherein the sheath is engaged by tissue surrounding the incision, and the expanding members slide beyond the sheath and into the right atrium, wherein the expanding members are released;

actuating the expanding members to an expanded condition to hold tissue away from the drainage port; and

withdrawing venous blood from the right atrium.

2. The method of claim **1**, further comprising the step of sealing the atrial appendage circumferentially around the cannula.

3. The method of claim **1**, wherein the venous drainage catheter further comprises a proximal side opening which communicates with the lumen of the cannula, a second cannula slidably disposed within the lumen of the first cannula and passing through said side opening, the distal end of the second cannula having an opening aligned longitudinally with the drainage port of the cannula, and wherein the expanding members are carried by the housing first cannula.

4. The method of claim **3**, wherein the step of inserting the cannula through the incision comprises the steps of:

inserting the first cannula through the incision and into the right atrium; and

inserting the second cannula through the proximal side opening and through the lumen of the first cannula, and advancing the second cannula distally into the atrium until the drainage port of the first cannula aligns with the opening on the distal end of the second cannula.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,270,490 B1
DATED : August 7, 2001
INVENTOR(S) : Kevin Hahnen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Claim 3,
Please delete [cannula, and wherein the expanding members are carried by the housing]

Signed and Sealed this

Sixteenth Day of April, 2002

Attest:

Attesting Officer

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

US006319251B1

(12) **United States Patent**
Tu et al.

(10) **Patent No.: US 6,319,251 B1**
(45) **Date of Patent: Nov. 20, 2001**

(54) **MEDICAL DEVICE AND METHODS FOR TREATING INTRAVASCULAR RESTENOSIS**

(76) Inventors: **Hosheng Tu; Steve Chun-Guang Tu,** both of 2151 Palermo, Tustin, CA (US) 92782

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/489,688**

(22) Filed: **Jan. 24, 2000**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/159,697, filed on Sep. 24, 1998, now Pat. No. 6,036,689.

(51) **Int. Cl.**[7] **A61B 18/18**
(52) **U.S. Cl.** **606/41**; 607/102; 607/122; 606/194; 606/198
(58) **Field of Search** 606/41–50, 190–192, 606/194, 198; 607/122, 101, 102, 113

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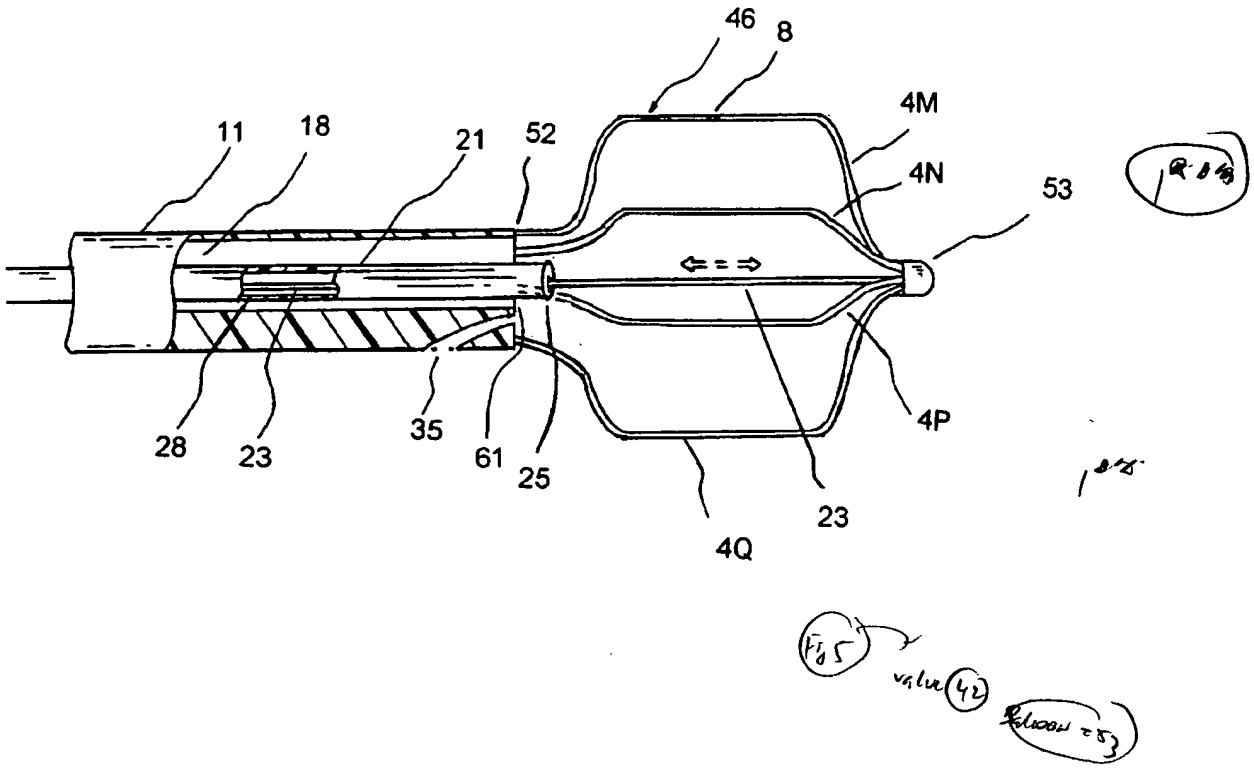
* cited by examiner

Primary Examiner—Linda C. M. Dvorak
Assistant Examiner—David M. Ruddy

(57) **ABSTRACT**

A medical device for treating intravascular restenosis of a patient, the medical device comprising a catheter shaft and an inner catheter, the inner catheter having a deployable wire assembly arrangement, wherein the deployable wire assembly arrangement comprises a plurality of preshaped expandable metallic basket members at the distal end of the inner catheter adapted to contact a pre-implanted stent and to apply RF current to the tissues for therapeutic purposes through a wire guide shaft. Alternately, a plurality of expandable metallic basket members are secured to the distal section of the catheter shaft for contacting a pre-implanted stent of the patient through a wire guide shaft.

16 Claims, 8 Drawing Sheets



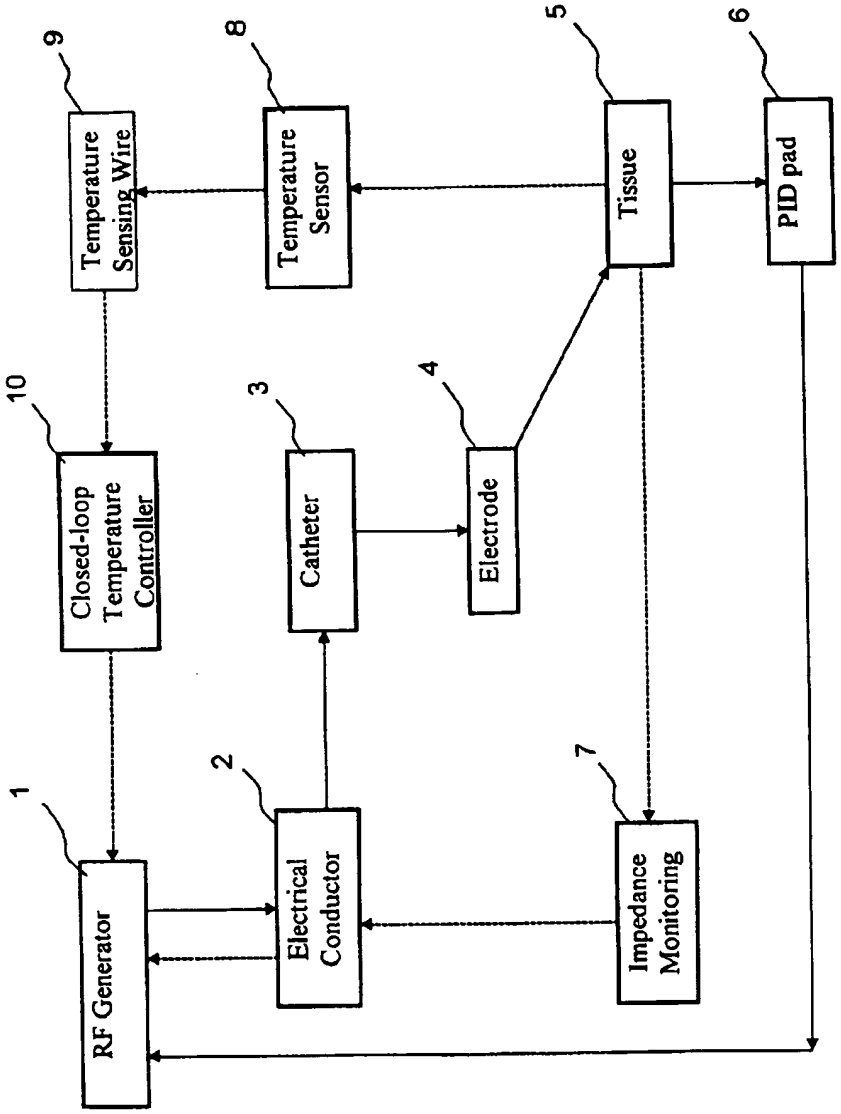

1
RF Generator
2
Electrical Conductor
3
Catheter
4
Electrode
5
Tissue
6
PID pad
7
Impedance Monitoring
8
Temperature Sensor
9
Temperature Sensing Wire
10
Closed-loop Temperature Controller

FIG. 1

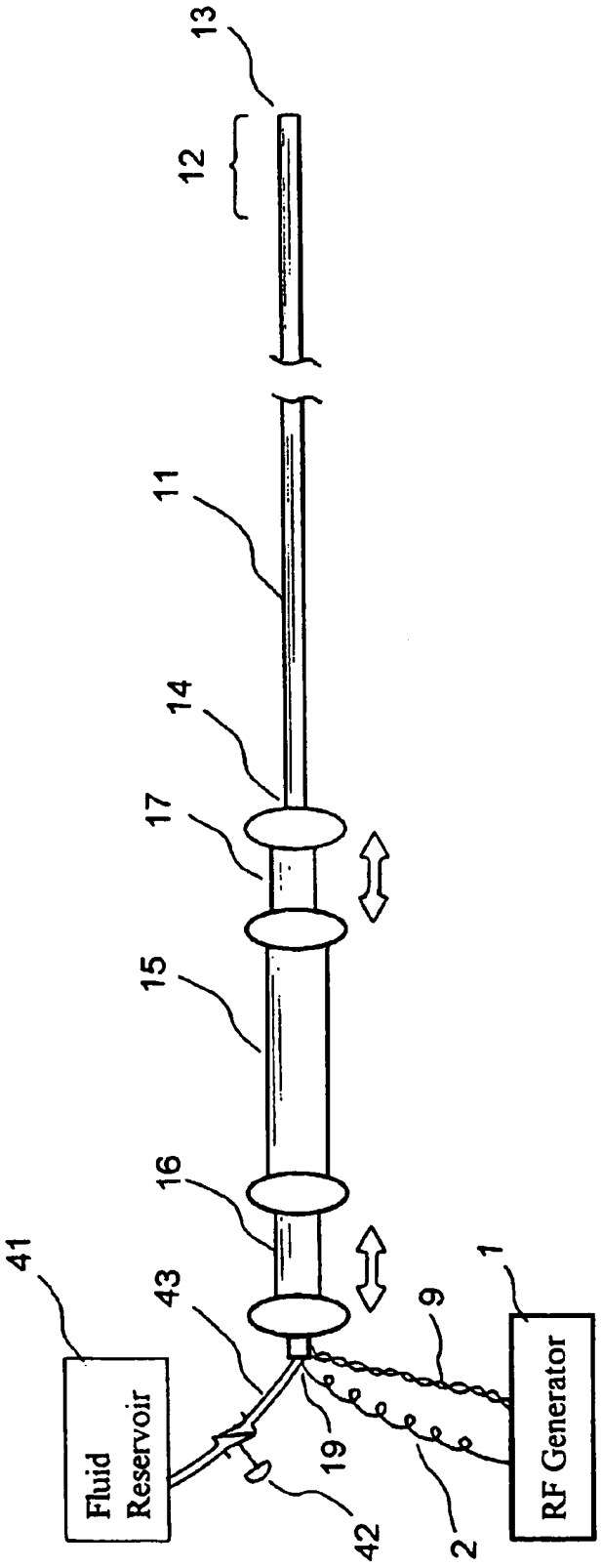

13
12
11
14
17
15
16
41
43
9
1
Fluid Reservoir
RF Generator
19
42
2

FIG. 2

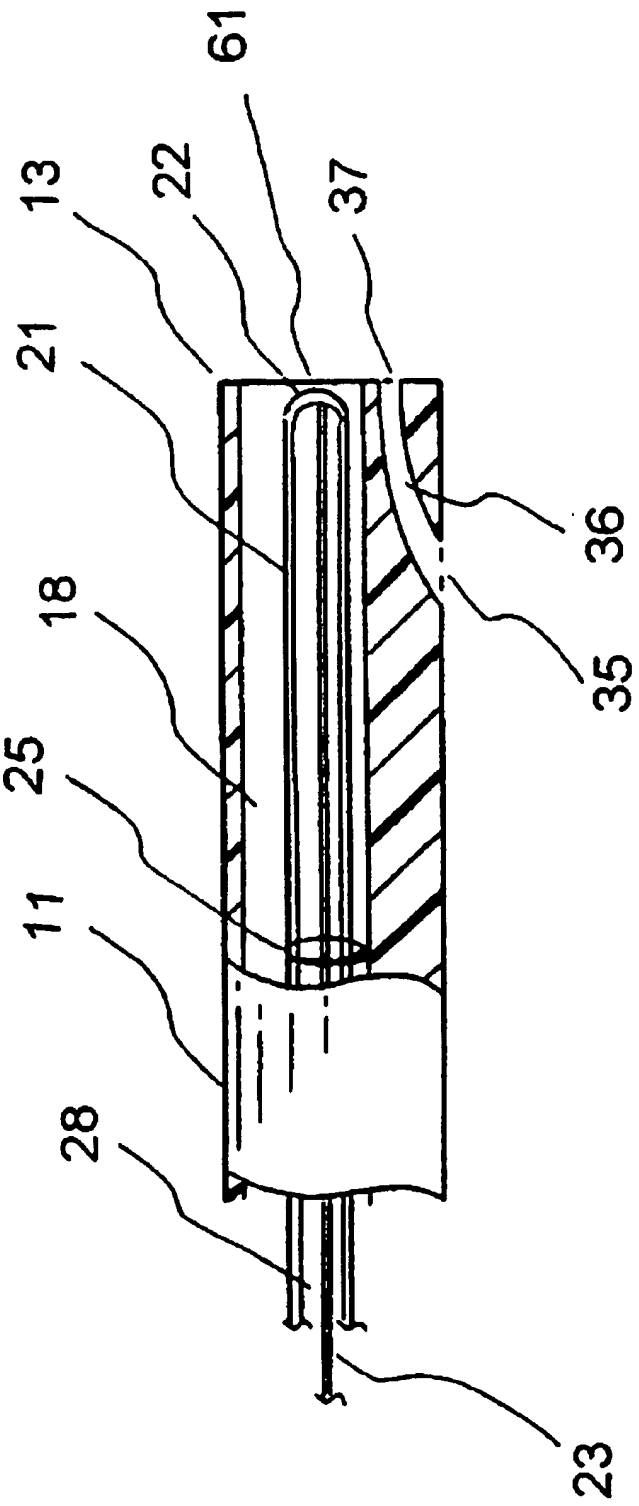


FIG. 3

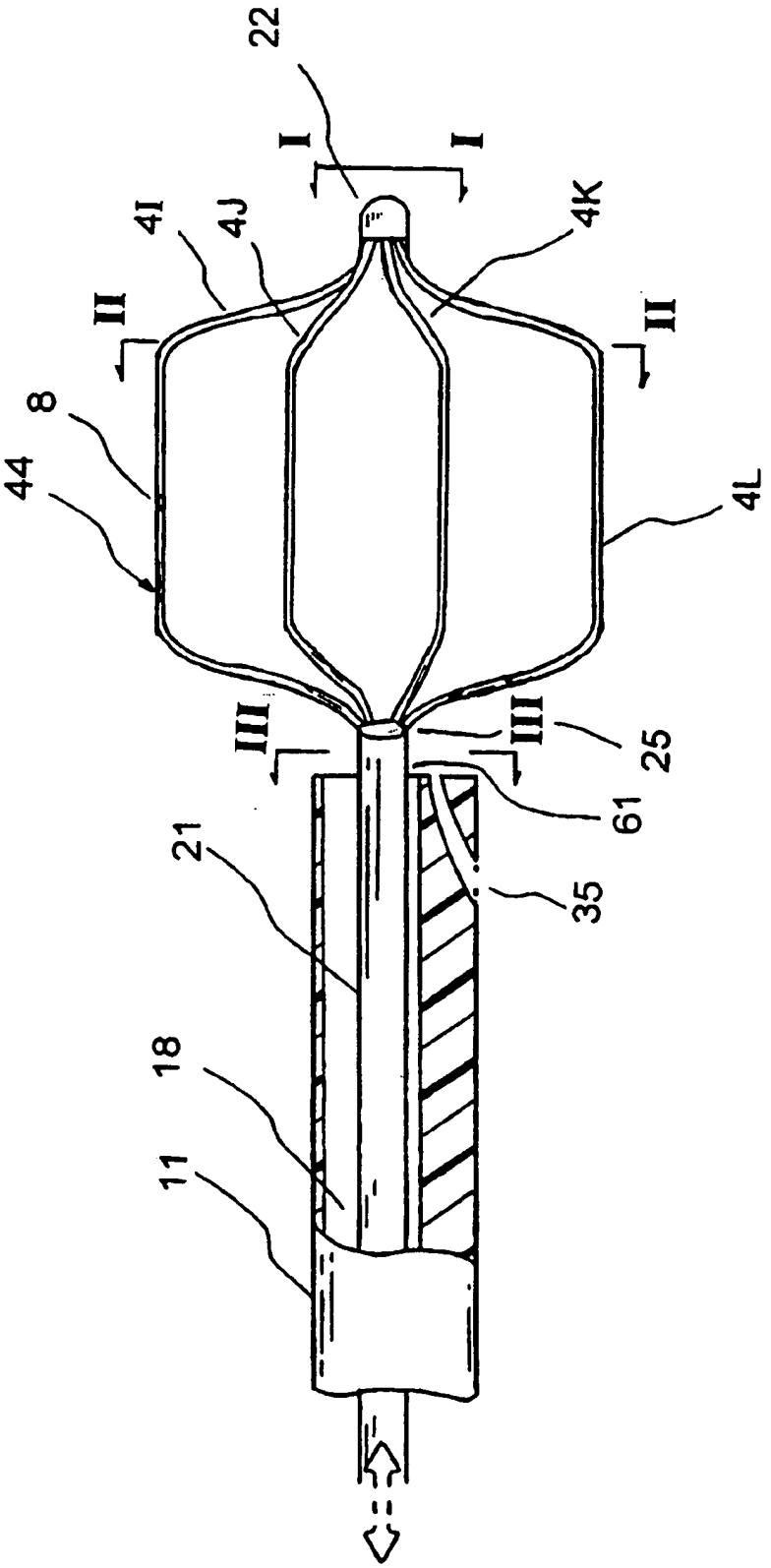


FIG. 4

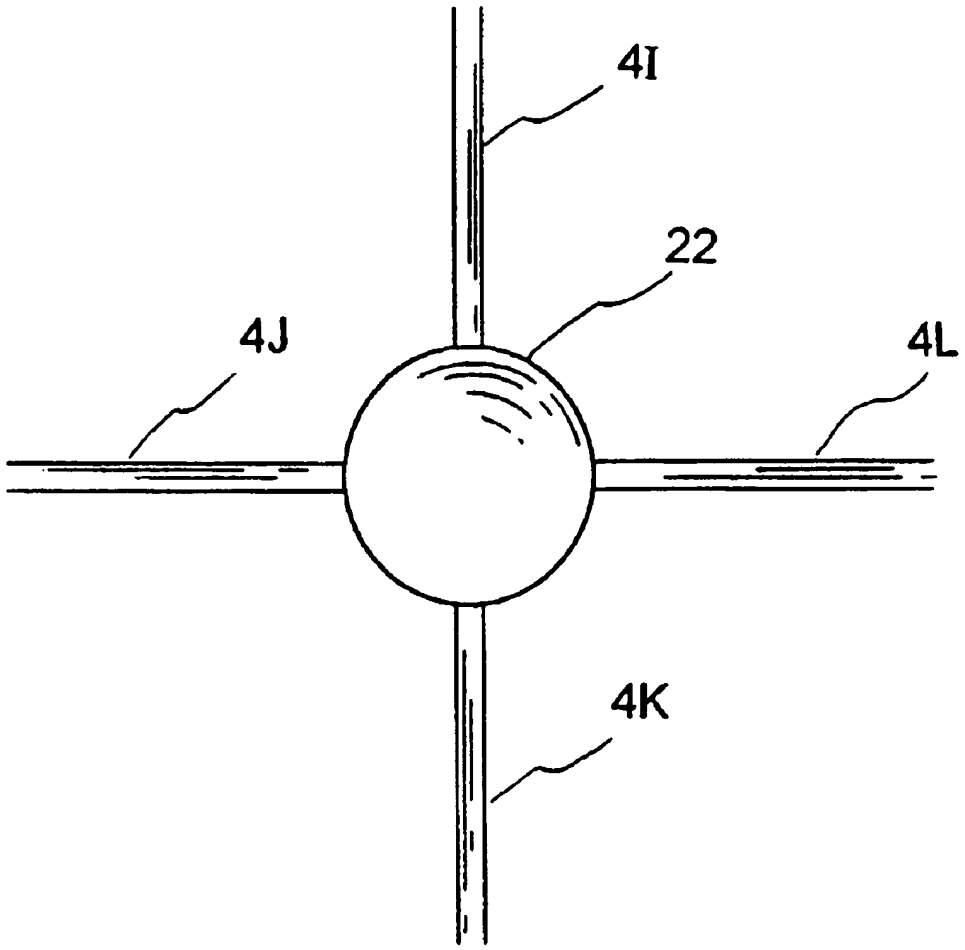


FIG. 4A

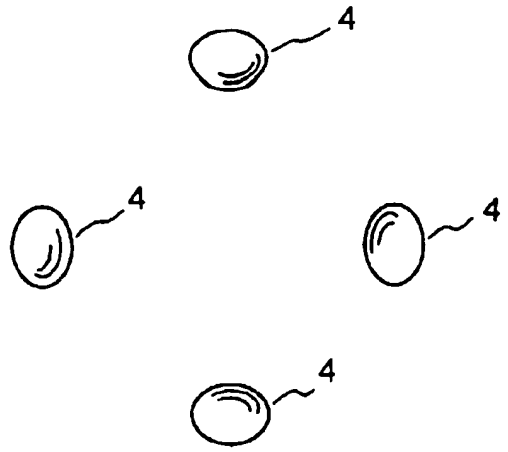


FIG. 4B

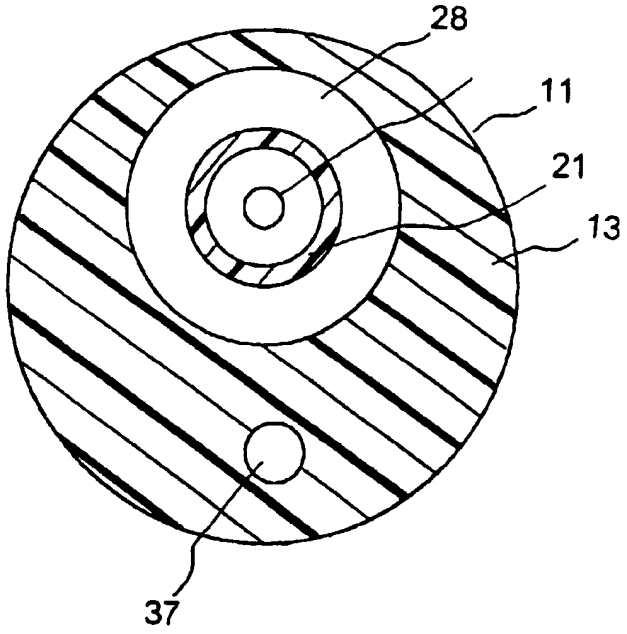
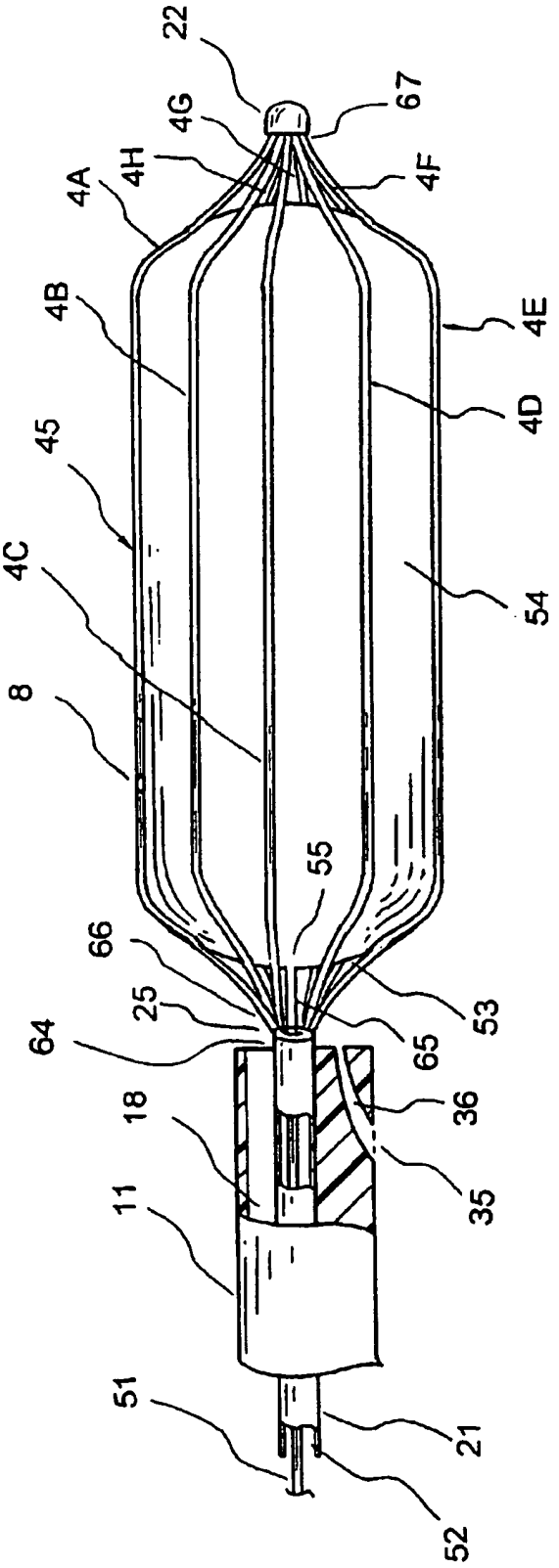


FIG. 4C


22
67
4G
4H
4F
4A
4B
4E
4D
45
4C
54
8
55
66
25
53
64
65
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36
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11
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21
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FIG. 5

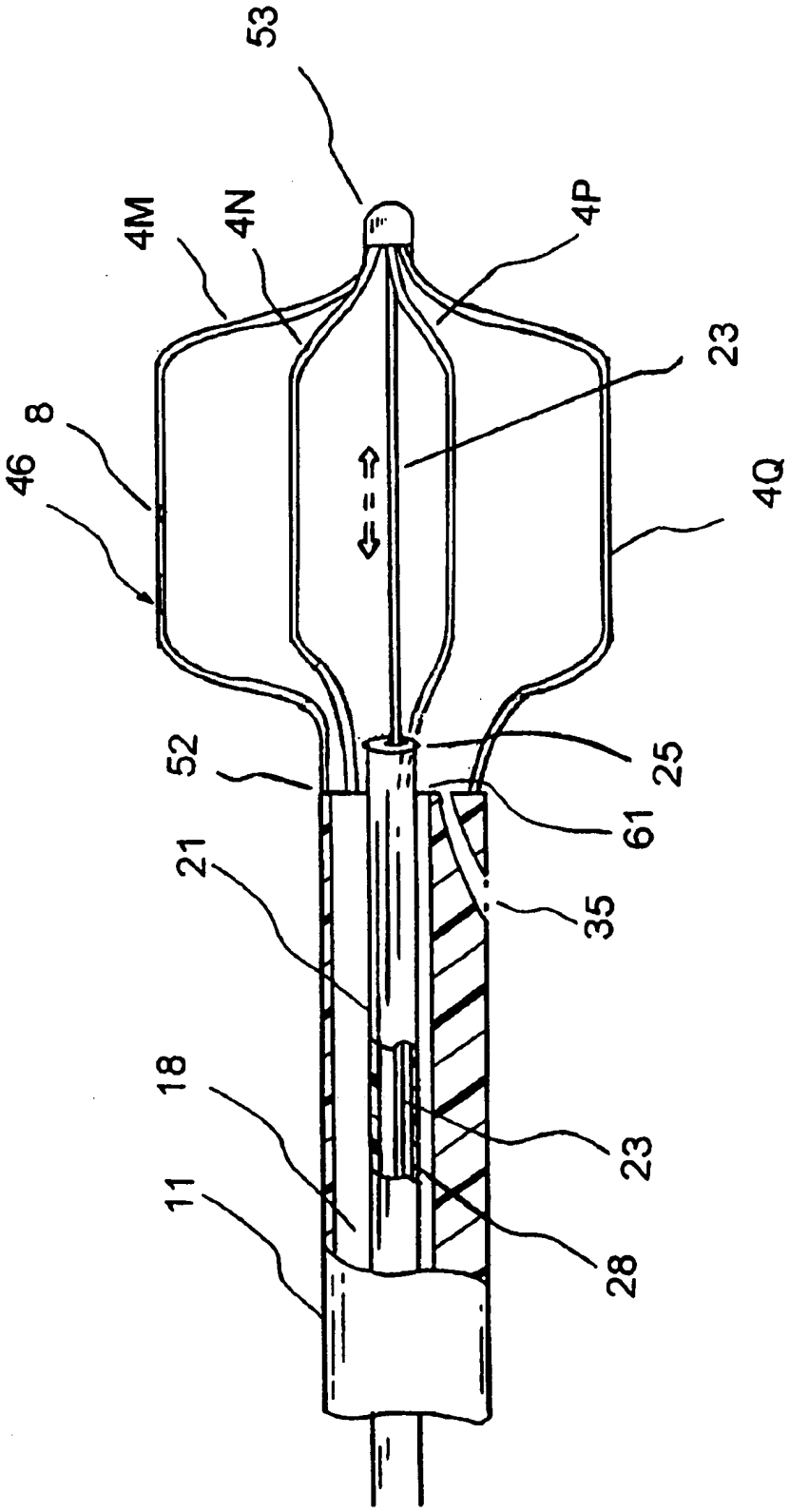

FIG. 6

MEDICAL DEVICE AND METHODS FOR TREATING INTRAVASCULAR RESTENOSIS

CROSS-REFERENCE TO RELATED APPLICATIONS

This patent application is a continuation-in-part application of application Ser. No. 09/159,697, entitled "Ablation Device for Treating Atherosclerotic Tissues" filed Sep. 24, 1998, U.S. Pat. No. 6,036,689 now allowed by the U.S. Patent Office, and is incorporated herein by reference.

TECHNICAL FIELD OF THE INVENTION

The present invention generally relates to improved medical device and methods for treating tissues, and more particularly, to such an ablation device and methods for treating atherosclerotic tissues in a patient by delivering therapeutic RF energy through an expandable basket structure having means for providing a plurality of continuous linear metallic wires assemble to the specific lesion sites.

BACKGROUND OF THE INVENTION

An artery is one of the tube-shaped blood vessels that carry blood away from a heart to the body's tissues and organs. An artery is made up of an outer fibrous layer, a smooth muscle layer, a connecting tissue layer, and the inner lining cells. If arterial walls become hardened due to the accumulation of fatty substances, then blood flow can be diminished. Hardening of the arteries, or loss of vessel elasticity, is termed arteriosclerosis while fatty deposit build-up is termed atherosclerosis. Atherosclerosis and its complications are a major cause of death in the United States. Heart and brain diseases are often the direct result of this accumulation of fatty substances that impair the arteries' ability to nourish vital body organs.

Recently, a new technique of inserting a metallic stenting element is used to permanently maintain the walls of the vessel treated at its extended opening state. Vascular stents are tiny mesh tubes or coils made of stainless steel or other metals and are used by heart surgeons to prop open the weak inner walls of diseased arteries. A catheter with a flexible guidewire-type tip is threaded up from the arm or groin through the artery until it reaches the blocked area. The stent is then deployed via an inflated balloon or via a delivery catheter. The deployed stent ruptures the plaque and increases the diameter of the blood vessel opening. The arterial passage is thus widened. As a result of enlarging the hardened plaque, cracks may unfortunately occur within the plaque to expose the underlying fresh tissue or denuded cells to the blood stream.

There are limitations, however, to this technique's application, depending on the extent of the disease, the blood flow through the artery, the part of the anatomy, and the particular vessels involved. Plaque build-up and/or severe re-stenosis recurrence within 6 months is generally up to 20–30 percent of those treated. The underlying newly exposed fresh collagen tissue or damaged cells still pose as a precursor for vessel reclosures or restenosis, regardless of stenting or not.

When a clogged artery is widened, the plaque or atheromatous material is broken up or split open while stretching the remaining soft parts of the vascular and perivascular tissue. Thus, stenting achieves its goal by creating a controlled but substantial injury to the vessel wall. However, the underlying collagen, tissue or damaged endothelium is exposed to the blood flow. Collagen has a pro-thrombotic

property, which is part of the body healing processes. Furthermore, collagen has been widely used in hemostat treatment owing to its clotting properties. Unless the newly exposed collagen or the damaged endothelium is passivated or modulated, the chance for blood vessel clotting as well as restenosis still exists. Moderate heat is known to tighten and shrink the collagen tissue as illustrated in U.S. Pat. Nos. 5,456,662 and 5,546,954. It is also clinically verified that thermal energy is capable of denaturing the tissue and modulating the collagenous molecules in such a way that treated tissue becomes more resilient ("The Next Wave in Minimally Invasive Surgery" MD&DI pp. 36–44, August 1998). Therefore, it becomes imperative to post-treat vessel walls after the walls have been treated with angioplasty and/or stenting procedures.

One method of reducing the size of cellular tissues in situ has been used in the treatment of many diseases, or as an adjunct to surgical removal procedures. This method applies appropriate heat to the tissues, and causes them to shrink and tighten. It can be performed on a minimal invasive fashion, which is often less traumatic than surgical procedures and may be the only alternative method, wherein other procedures are unsafe or ineffective. Ablative treatment devices have an advantage because of the use of a therapeutic energy that is rapidly dissipated and reduced to a non-destructive level by conduction and convection, to other natural processes.

RF therapeutic protocol has been proven to be highly effective when used by electrophysiologists for the treatment of tachycardia; by neurosurgeons for the treatment of Parkinson's disease; and by neurosurgeons and anesthetists for other RF procedures such as Gasserian ganglionectomy for trigeminal neuralgia and percutaneous cervical cordotomy for intractable pains. Radiofrequency treatment, which exposes a patient to minimal side effects and risks, is generally performed after first locating the tissue sites for treatment. Radiofrequency energy, when coupled with a temperature control mechanism, can be supplied precisely to the device-to-tissue contact site to obtain the desired temperature for treating a tissue.

To effect the optimal ablation, it requires selection of the most appropriate device-to-tissue contact site as well as the most effective contact surface area. Several recent patents disclose a catheter in a basket structure having means for providing a plurality of discrete and isolated point electrodes. The patents include U.S. Pat. No. 4,699,147 to Chilson et al., U.S. Pat. No. 5,156,151 to Imran, U.S. Pat. No. 5,255,679 to Imran, U.S. Pat. No. 5,345,936 to Pomeranz et al., U.S. Pat. No. 5,411,025 to Webster, Jr., U.S. Pat. No. 5,628,313 to Webster, Jr., U.S. Pat. No. 5,636,634 to Kordis et al., and U.S. Pat. No. 5,672,153 to Lax et al. However, all of the above-identified patents comprise a non-conductive spacing between any two electrodes. A major drawback of those patents is obvious because of its limited electrode contact surface to the tissues for delivering heat therapy.

McGee et al. in U.S. Pat. No. 5,722,403 discloses a combination of a balloon and electrode arrangement for treating tissue. However, McGee et al. does not disclose a medical device comprising a plurality of continuous wire electrodes for contacting an implanted stent to treat the underlying exposed tissue for minimizing intravascular restenosis.

A stent deployed within a vessel, such as a coronary stent, has excellent metal-to-tissue contact surface. It becomes an ideal medium for applying thermal energy to the specific

tissue that has been enlarged and has newly tissue exposed. The metal-to-tissue contact site is the tissue region that most urgently needs heat treatment or modulation. A RF delivery means for contacting the metallic stenting element is useful in this case to shrink and tighten the target tissue for treating intravascular restenosis. Particularly, a wire assembly arrangement comprising a plurality of deployable metallic members, such as the long continuous wires on a basket-type catheter shaft, is useful for delivering the RF thermal energy to the denuded collagen or damaged endothelium via a pre-implanted stent to shrink and tighten the target tissue after a stent-assisted angioplasty procedure.

Therefore, there is a need for an improved medical device having the capability to effectively contact the inner walls of a tubular vessel via a pre-implanted stent using the radiofrequency energy to treat an enlarged artery or other tissues, such as esophagus, larynx, ureter, urethra and the like.

SUMMARY OF THE INVENTION

In general, it is an object of the present invention to provide a method and an improved medical ablation device for generating heat, to treat the atherosclerotic vascular vessels, or other tissues/organs, such as intestine, colon, uterus, urethra tube, and the like. It is another object of the present invention to provide a method and a device for monitoring the temperature of the ablated tissue, and to control the temperature by utilizing a temperature control mechanism and/or algorithm. The location of the temperature sensor means is preferably at close proximity of the metal-to-tissue contact sites of the ablation device. It is still another object of this invention to provide a method and an device for treating atherosclerotic tissues, vascular walls, or tubular cellular tissues by applying RF current to the metallic members of a basket-type catheter system having a plurality of metallic wires assembly arrangement and subsequently to the underlying tissues. It is a further object of the present invention to apply RF current via a basket-like wire assembly arrangement through a pre-implanted stent to the underlying tissue for therapeutical purposes.

Briefly, heat is generated by supplying a suitable RF energy source to a device having a RF current delivery arrangement, combining with a pre-implanted stent as an electrode arrangement for contacting the body tissues. "An electrode arrangement" is defined in this invention as a combination of a metallic structure that is accessible to a RF current source and a pre-implanted stent, wherein the pre-implanted stent in a patient is not part of the medical device of the present invention. The medical device system comprising a metallic structure is generally referred to as a flexible catheter having a plurality of basket members, wherein each basket member is a linear continuous metallic wire arrangement. Each basket member may be in a mesh form, a coil form, a curved wire form, or other appropriate form, used to contact the pre-implanted stent. The basket member of this invention that has a continuous conductive wire arrangement is different from a conventional electrophysiology catheter which usually has a plurality of electrodes, the electrodes being separated by a non-conducting zone.

The energy can be applied to the metallic basket member and subsequently to the atherosclerotic vascular walls or cellular tissues through the pre-implanted stent in a patient. A DIP (dispersive indifferent pad) type pad or electrode that contacts the patient, is connected to the Indifferent Electrode Connector on the RF generator. Therefore, the RF current delivery becomes effective when a close circuit from a RF generator through a patient and returning to the RF generator is formed. Heat is controlled by the power of the RF current delivered, by the delivery duration, and by the delivery mode. The standard RF current generator and its applications through the electrode arrangement to a patient are well known for those who are skilled in the art.

In an optional embodiment, means for generating vibration at the distal section comprises a motor mounted in the cavity of the handle, which has a rotatable motor shaft, an elongated connecting shaft having a first end, to which the distal end portion of the catheter shaft is connected, and a second end connected to the handle, a weight eccentrically mounted on the motor shaft with respect to the motor shaft axis, so as to rotate eccentrically, so that when the motor shaft rotates, the distal end portion of the device vibrates.

In one embodiment, the medical device comprises a deployable wire assembly arrangement, wherein the wire assembly arrangement and a pre-implanted stent of a patient forms an electrode arrangement for delivering RF current to a tissue for treating intravascular restenosis. In a preferred embodiment, the medical device system for treating intravascular restenosis comprises a flexible catheter shaft having a distal section, a shaft distal end, a shaft proximal end, and at least one lumen extending between the shaft proximal end and the shaft distal end, wherein the at least one lumen has at least one opening at the shaft distal end. A handle is attached to the shaft proximal end, wherein the handle has a cavity. In one embodiment, the medical device system may further comprise an inner catheter located inside the at least one lumen of the catheter shaft, wherein the inner catheter comprises a distal end and a proximal end.

The wire assembly arrangement may be mounted at the distal end of the inner catheter, wherein the wire assembly arrangement comprises a plurality of preshaped expandable metallic basket members, each metallic basket member having a member distal end, a member proximal end, wherein the member proximal ends of the preshaped expandable metallic basket members are joined at the distal end of the inner catheter and wherein the member distal ends of the preshaped expandable metallic basket members are joined at a distal joint. Furthermore, a wire assembly deployment mechanism for deploying the wire assembly arrangement is mounted on the handle, wherein the wire assembly deployment mechanism is coupled to the proximal end of the inner catheter, wherein the plurality of preshaped expandable metallic basket members are expanded at a deployed state, and wherein the plurality of preshaped expandable metallic basket members are retracted at a non-deployed state. The electrode arrangement is connected to an external RF generating means through an electrical conductor.

The medical device system may further comprise a wire guide shaft at the distal section of the catheter shaft, the wire guide shaft having a proximal end and a distal end, wherein the wire guide shaft defines a wire guide lumen, wherein the wire guide lumen has at least one opening at the distal end and at least one opening at the proximal end of the wire guide shaft, wherein the wire guide shaft is used for introducing said medical device system into a vascular vessel over a guidewire.

A method for treating intravascular restenosis of a patient having a pre-implanted stent, the method comprises delivering RF current to the pre-implanted stent so as to provide thermal therapy to the intravascular tissue for treating intravascular restenosis.

In another preferred embodiment, a medical device system for delivering RF current to a pre-implanted stent

comprises a flexible catheter shaft having a distal section, a shaft distal end, a shaft proximal end, and at least one lumen extending between the shaft proximal end and the shaft distal end, wherein the at least one lumen has at least one opening at the shaft distal end of the catheter shaft. A handle is attached to the shaft proximal end of the catheter shaft, wherein the handle has a cavity. A wire assembly arrangement is mounted at the distal section of the catheter shaft, wherein the wire assembly arrangement comprises a plurality of preshaped expandable metallic basket members, each metallic basket member having a member distal end, a member proximal end, wherein the member proximal ends of the preshaped expandable metallic basket members are joined at the distal end of the catheter shaft and wherein the member distal ends of the preshaped expandable metallic basket members are joined at a basket distal joint. Furthermore, a wire assembly deployment mechanism for deploying the wire assembly arrangement is mounted on the handle, wherein the wire assembly deployment mechanism comprises an elongated element inside the at least one lumen of the catheter shaft, wherein a distal end of the elongated element is secured to the basket distal joint, wherein the plurality of preshaped expandable metallic basket members is expanded at a deployed state, and wherein the plurality of preshaped expandable metallic basket members is retracted at a non-deployed state.

The medical device comprises an external RF current generator, wherein the RF current is supplied to the wire assembly arrangement through an electric conductor for contacting a pre-implanted stent, wherein the wire assembly arrangement and the pre-implanted stent forms an electrode arrangement for delivering RF current to a tissue for therapeutic purposes.

The method and medical device of the present invention has several significant advantages over other known systems or techniques to treat the atherosclerotic tissues after the tissue is enlarged by an implanted stent. In particular, the device system comprising a deployable wire assembly arrangement having a plurality of linear continuous metallic wire arrangement for contacting a pre-implanted stent and using RF energy as a heat source in this invention results in a more efficient therapeutic effect, which is highly desirable in its intended applications.

BRIEF DESCRIPTION OF THE DRAWINGS

Additional objects and features of the present invention will become more apparent and the invention itself will be best understood from the following Detailed Description of Exemplary Embodiments, when read with reference to the accompanying drawings.

FIG. **1** is a schematic diagram of a RF treatment method in relation to the tissue or atherosclerotic tissue through an electrode arrangement in a patient.

FIG. **2** is an overall view of the medical device system having a deployable wire assembly arrangement and a RF generator, constructed in accordance to the principles of the present invention.

FIG. **3** is a cross-sectional view of the distal end portion of the device, the device having a deployable wire assembly arrangement positioned within the lumen of a flexible catheter shaft at a non-deployed state.

FIG. **4** is a cross-sectional view of the distal end portion of the device, the device having a deployable wire assembly arrangement comprising a plurality of preshaped expandable metallic basket members at a deployed state.

FIG. **4A** is a transverse view, section I—I of FIG. **4**.

FIG. **4B** is a transverse view, section II—II of FIG. **4**.

FIG. **4C** is a transverse view, section III—III of FIG. **4**.

FIG. **5** is a cross-sectional view of the distal end portion of a preferred medical device, the device having a deployable wire assembly arrangement comprising a plurality of expandable metallic basket members wrapped onto and around an inflatable balloon at a deployed state.

FIG. **6** is a cross-sectional view of the distal end portion of another preferred medical device, the device having a deployable wire assembly arrangement positioned at the distal section of a flexible catheter shaft at a deployed state.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Referring to FIGS. **1** to **6**, what is shown is an embodiment of the medical device system, comprising applying radiofrequency energy therapy to treat the atherosclerotic vascular vessels, or other tubular cellular tissues of a patient through a basket-type medical device comprising a plurality of preshaped expandable metallic basket members and a pre-implanted stent of a patient.

FIG. **1** shows a schematic diagram of a RF treatment method in relation to the tissues or atherosclerotic tissues through an electrode arrangement in a patient. Since the patient already has a pre-implanted stent, the electrode arrangement is referred to hereby as a combination of a metallic structure of the medical device that is accessible to a RF current source and the pre-implanted stent. The metallic structure of the present invention may include a wire assembly arrangement comprising a plurality of metallic basket members for contacting the pre-implanted stent in a patient, wherein the metallic basket member has no non-conductive zone along a majority portion of the member. A RF generator **1** is connected to a catheter or a medical device **3** through an electrical conductor **2**. An electrode arrangement **4** of the catheter **3** is to contact the tissue **5** of a patient when the device is deployed. The pre-implanted stent portion of the electrode arrangement **4** is in close contact with the underlying tissue **5**. A DIP (dispersive indifferent pad) type pad **6** that contacts a patient is connected to the Indifferent Electrode Connector on the RF generator **1**. Therefore, the RF current delivery becomes effective when a close circuit from a RF generator through a patient and returning to the RF generator is formed. Impedance **7** measured from the tissue contact may be used to ensure good tissue contact for tissue treatment, otherwise the RF current is cut off when the impedance is unreasonably high. A temperature sensor **8** may be used to measure the tissue temperature and is relayed through a temperature sensing wire **9** and a closed-loop temperature controller **10** for controlling the ablative energy delivered. Energy is controlled by the power of the RF current delivered, power delivery mode, and the delivery duration.

As shown in FIGS. **2** and **3**, one preferred embodiment of the medical device system comprises a catheter shaft **11**, the catheter shaft having a distal section **12**, a shaft distal end **13**, a shaft proximal end **14**, and at least one lumen **18** extending between the shaft proximal end **14** and the shaft distal end **13**, wherein the at least one lumen **18** may have at least one opening **61** at the shaft distal end **13** of the catheter shaft **11**. A handle **15** is attached to the shaft proximal end **14** of the catheter shaft **11**, wherein the handle **15** has a cavity.

In one preferred embodiment, an inner catheter **21** is located inside the at least one lumen **18** of the catheter shaft **11**, wherein the inner catheter **21** comprises a distal end **25** and a proximal end. A wire assembly arrangement **44** is

mounted at the distal end **25** of the inner catheter **21**, wherein the wire assembly arrangement **44** may comprise either a plurality of non-preshaped expandable metallic basket members **4A–4B** for wrapping around an inflatable balloon or a plurality of preshaped expandable metallic basket members **4I–4L** and/or **4M–4Q**, each metallic basket member having a member distal end, a member proximal end, wherein the member proximal ends of the expandable metallic basket members are joined at the distal end **25** of the inner catheter **21** and wherein the member distal ends of the expandable metallic basket members are joined at a distal joint **22**.

A wire assembly deployment mechanism **17** may be mounted on the handle **15**, wherein the wire assembly deployment mechanism **17** is attached to the proximal end of the inner catheter **21**, wherein the plurality of preshaped expandable metallic basket members are expanded at a deployed state, and wherein the plurality of preshaped expandable metallic basket members are retracted at a non-deployed state. During the insertion into or removal of the medical device from a patient, the wire assembly arrangement is at a non-deployed state.

The medical catheter system of the present invention further comprises a RF current generating means **1** for generating RF current, wherein the RF current is supplied to the wire assembly arrangement **44**, **45**, **46** for therapeutic purposes. The RF current is supplied through an electric conductor **2** for contacting a pre-implanted stent in a patient. The wire assembly arrangement **44**, **45**, **46** and the pre-implanted stent forms an electrode arrangement **4** for delivering RF current to a tissue for treating intravascular restenosis. In an alternate embodiment as shown in FIG. **5**, a fluid reservoir **41** may be provided for delivering pressurized working fluid through a control valve **42** and a conveying duct **43** to the inflatable balloon **53**.

FIG. **3** shows a cross-sectional view of the distal end portion **12** of the device, wherein the device has a deployable wire assembly arrangement **44** positioned within the lumen **18** of the inner catheter **21** at a non-deployed state. In one embodiment, the shaft distal end **13** has two lumens **18** and **36**. One lumen **18** is used by the deployable inner catheter **21**. The other lumen **36**, a wire guide lumen is used to tract and ride on a previously inserted guidewire to the lesion site. In an alternate embodiment, the medical device of the present invention rides on an existing guidewire to the target site **5** for ablation operation.

An insulated electrical conductor **2** or the inner catheter itself **21** serving as a conducting means passes through the lumen **18** of the catheter shaft **11** and is connected to the wire assembly arrangement **44**. The other end of the electrical conductor is connected to an external RF generator **1**.

FIG. **4** shows a cross-sectional view of the distal end portion of the device, wherein the device has a deployable wire assembly arrangement **44** comprising a plurality of preshaped expandable metallic basket members at a deployed state. The deployment operation is initiated at the wire assembly deployment mechanism **17** at the handle **15**. The deployed plurality of metallic basket members **4I**, **4J**, **4K**, **4L** are fully extended radially to contact an inside surface of the pre-implanted stent, as a result of its preshaped memory. This portion of the deployed metallic basket members is made of conductive material, which is externally connected to the RF current source through an insulated electrical conductor. Other portion of the catheter shaft and the surface of the inner catheter are generally not conductive.

In one embodiment, at least one temperature sensing means **8** may be disposed at close proximity of the wire assembly arrangement **44**. Insulated temperature sensor wire means **9** passes from the temperature sensing means **8**, to an external temperature control mechanism **10** through an outlet connector **19**. The RF current delivery is controlled by using the measured temperature from the temperature sensing means **8**, through a closed-loop temperature control mechanism **10** and/or algorithm. When the measured temperature rises to a preset high-limit point, the temperature control mechanism sends out a signal to cut off the RF current supply. In a similar manner, when the measured temperature drops to a preset low-limit point, the temperature control mechanism sends about a signal to activate the RF current supply.

FIG. **4A** shows a transverse view, section I—I of FIG. **4**. The distal ends of all metallic basket members **4I**, **4J**, **4K**, and **4L** are secured to a distal joint **22**. FIG. **4B** shows a transverse view, section II—II of FIG. **4**. In one optional embodiment, the cross-section of the metallic basket members is an oval shape or flat shape. FIG. **4C** shows a transverse view, section III—III of FIG. **4**. In a preferred embodiment, a portion of the preshaped expandable metallic basket members is essentially straight at a deployed state.

FIG. **5** shows a cross-sectional view of the distal end portion of an alternate medical device, wherein the device has a deployable wire assembly arrangement **45** comprising a plurality of expandable metallic basket members wrapped onto and around an inflatable balloon at a deployed state. The alternate medical device system comprises a catheter shaft **11** having a distal section **12**, a shaft distal end **13**, a shaft proximal end **14**, and at least one lumen **18** extending between the shaft proximal end **14** and the shaft distal end **13**, wherein the at least one lumen **18** has at least one opening **64** at the shaft distal end **13** of the catheter shaft **11**.

A handle **15** is attached to the shaft proximal end **14** of the catheter shaft **11**, wherein the handle has a cavity. An inner catheter **21** is located inside the at least one lumen **18** of the catheter shaft **11**, wherein the inner catheter **21** comprises a distal end **25**, a proximal end, and at least one lumen **52** extending between the distal end and the proximal end. An inflation tubing **65** is an extension of an inflation lumen **51**, wherein the inflation lumen **51** is located within the inner catheter **21** and is communicated to the external fluid reservoir **41** through the fluid conveying duct **43**. The inflation tubing **65** extends distally to the distal end **25** of the inner catheter **21**, the inflation tubing **65** having a proximal end and a distal end **55**.

The alternate medical device further comprises an inflatable balloon **53** having a proximal end and a distal end, wherein the distal end **55** of the inflation tubing **65** opens into and is in communication with an interior of the inflatable balloon **53**, the distal end of the inflatable balloon **53** is sealed. In the alternate medical device system, a wire assembly arrangement **45** is mounted at the digtal end **25** of the inner catheter **21**, wherein the wire assembly arrangement comprises a plurality of expandable metallic basket members **4A–4H** wrapped onto and around the inflatable balloon **53**, each expandable metallic basket member having a member distal end **67** and a member proximal end **66**, wherein the member proximal ends of the expandable metallic basket members are joined at the distal end **25** of the inner catheter **21** and wherein the basket distal ends of the expandable metallic basket members are joined at a distal joint **22**. A wire assembly deployment mechanism **17** is mounted on the handle **15**, wherein the wire assembly deployment mechanism **17** is attached to the proximal end of the inner catheter **21**, wherein the plurality of expandable metallic basket members is expanded at a deployed state,

and wherein the plurality of expandable metallic basket members is retracted at a non-deployed state.

As shown in FIG. 6, the medical device system may further comprise a lumen **28** between the proximal end and the distal end **25** of the inner catheter **21**, and further comprises a connecting shaft **23** inside said lumen **28** of the inner catheter **21**. The connecting shaft **23** has a distal end and a proximal end, wherein the distal end of the connecting shaft **23** is joined to the distal joint **53** of the metallic basket members, and wherein the proximal end of the connecting shaft is secured to the wire assembly deployment mechanism **17**. A special push-pull controller **16** or the like on the handle adapted for the push-pull operation of the connecting shaft **23** is part of the wire assembly deployment mechanism **17**. The wire assembly arrangement **46** is mounted at the distal section of the catheter shaft, wherein the wire assembly arrangement comprises a plurality of preshaped expandable metallic basket members **4M, 4N, 4P, 4Q**, each metallic basket member having a member distal end, a member proximal end, wherein the member proximal ends of the preshaped expandable metallic basket members are joined at the distal end **52** of the catheter shaft **11** and wherein the member distal ends of the preshaped expandable metallic basket members are joined at a basket distal joint **53**.

The medical device system also comprises a RF current generating means **1**, wherein the RF current is supplied to the electrode arrangement **45** for therapeutic purposes.

The medical device system further comprises a wire guide shaft at the distal section **12** of the catheter shaft **11**, the wire guide shaft defining a wire guide lumen **36**, the wire guide shaft having a proximal end **35** and a distal end **37**, wherein the wire guide lumen **36** hag at least one opening at the distal end and at least one opening at the proximal end of the wire guide shaft, wherein the wire guide shaft is used for introducing the medical device system into a vascular vessel over a guidewire. The wire guide lumen **36** may be located close to one side of the wire guide shaft for rapid exchange of the medical device system over the guidewire.

Alternatively, the medical device system may comprise a wire guide shaft at the distal section of the catheter shaft, the wire guide shaft defining a wire guide lumen, wherein the wire guide lumen is connected to and in communication with the at least one lumen **18** of the catheter shaft **11**, the wire guide shaft having a proximal end and a distal end, wherein the wire guide shaft is used for introducing said medical device system into a vascular vessel over a guidewire.

A method for treating atherosclerotic tissues of a patient using a medical device system is illustrated. The medical device system may comprise a catheter shaft **11** and an inner catheter **21**, the inner catheter having a proximal end, a distal end and a deployable wire assembly arrangement **44, 45, 46** mounted at the distal end of the inner catheter, wherein the wire assembly arrangement comprises a plurality of preshaped expandable metallic basket members, each metallic basket member having a member distal end, a member proximal end, wherein the member proximal ends of the metallic basket members are joined at the distal end of the inner catheter and wherein the member distal ends of the metallic basket members are joined at a distal joint. The device system further comprises a RF current generating means, wherein the RF current is supplied to the wire assembly arrangement. The method comprises the steps of: (a) inserting the medical device through an artery or a vein to the location of the atherosclerotic tissues; (b) deploying the wire assembly arrangement to expand the preshaped expandable metallic basket members adapted to contact a pre-implanted stent; and (c) applying RF current to the electrode arrangement to effect treatment of the atherosclerotic tissues.

As an alternative illustration, a method for treating atherosclerotic tissues of a patient using a medical device system of the present invention is illustrated. The method comprises the steps of: (a) inserting the medical device through an artery or a vein to the location of the atherosclerotic tissues; (b) deploying the wire assembly arrangement to expand the expandable metallic basket members adapted to contact a pre-implanted stent; and (c) applying RF current to the electrode arrangement to effect treatment of the atherosclerotic tissues. The alternate medical device system for delivering RF current to a pre-implanted stent may comprise a flexible catheter shaft having a distal section, a shaft distal end, a shaft proximal end, and at least one lumen extending between the shaft proximal end and the shaft distal end, wherein the at least one lumen has at least one opening at the shaft distal end of the catheter shaft.

A handle is attached to the shaft proximal end of the catheter shaft, wherein the handle has a cavity. A wire assembly arrangement is mounted at the distal section of the catheter shaft, wherein the wire assembly arrangement comprises a plurality of preshaped expandable metallic basket members, each metallic basket member having a member distal end, a member proximal end, wherein the member proximal ends of the preshaped expandable metallic basket members are joined at the distal end of the catheter shaft and wherein the member distal ends of the preshaped expandable metallic basket members are joined at a basket distal joint. A wire assembly deployment mechanism is mounted on the handle, wherein the wire assembly deployment mechanism comprises an elongated element inside the at least one lumen of the catheter shaft, wherein a distal end of the elongated element is secured to the basket distal joint, wherein the plurality of preshaped expandable metallic basket members is expanded at a deployed state, and wherein the plurality of preshaped expandable metallic basket members is retracted at a non-deployed state.

The external RF current generator means has the capability to supply RF current by controlling the time, power, and temperature through an optional separate closed-loop temperature control means. The patient is connected to the RF generator means through a DIP electrode to form a closed-loop current system. Therefore, RF current is supplied and delivered to the targeted atherosclerosis region, through the electrode arrangement of this invention. The radiofrequency energy current in this invention is preferably within the range of 50 to 2,000 kHz. The frequency of the vibration of the medical device in this invention is preferably within the range of 60 to 1000 cycles per minute. By simultaneously applying RF energy to the electrode arrangement and by applying the vibrational pressure therapy, the atherosclerotic tissues can be treated.

In a particular embodiment, the material for the wire assembly arrangement of this invention consists of conductive metals such as platinum, iridium, gold, silver, stainless steel, Nitinol, or an alloy of these metals.

From the foregoing description, it should now be appreciated that a medical device system for the tubular organs, atherosclerotic tissues, and the treatment of vascular tissues, comprising a suitable energy source and a pre-implanted stent has been disclosed. While the invention has been described with reference to a specific embodiment, the description is illustrative of the invention and is not to be

construed as limiting the invention. Various modifications and applications may occur to those who are skilled in the art, without departing from the true spirit and scope of the invention, as described by the appended claims.

What is claimed is:

1. A medical device system for treating intravascular restenosis comprising:

a flexible catheter shaft having a distal section, a shaft distal end, a shaft proximal end, and at least one lumen extending between the shaft proximal end and the shaft distal end, wherein the at least one lumen has at least one opening at the shaft distal end;

a handle attached to the shaft proximal end, wherein the handle has a cavity;

an inner catheter located inside the at least one lumen of the catheter shaft, wherein the inner catheter comprises a distal end and a proximal end;

a wire assembly arrangement mounted at the distal end of the inner catheter, wherein the wire assembly arrangement comprises a plurality of preshaped expandable metallic basket members, wherein at least a portion of the preshaped expandable metallic basket members is essentially straight adapted for contacting a pre-implanted stent for treating intravascular restenosis, each metallic basket member having a member distal end, a member proximal end, wherein the member proximal ends of the preshaped expandable metallic basket members are joined at the distal end of the inner catheter and wherein the member distal ends of the preshaped expandable metallic basket members are joined at a distal joint;

a wire assembly deployment mechanism mounted on the handle, wherein the wire assembly deployment mechanism is coupled to the proximal end of the inner catheter, wherein the plurality of preshaped expandable metallic basket member are expanded at a deployed state, and wherein the plurality of preshaped expandable metallic basket members are retracted at a non-deployed state;

a wire guide shaft at the distal section of the catheter shaft, the wire guide shaft having a proximal end and a distal end that the wire guide shaft defines a wire guide lumen, wherein the wire guide lumen has at least one opening at the distal end and at least one opening at the proximal end of the wire guide shaft wherein the wire guide shaft is used for introducing said medical device system into a vascular vessel over a guidewire; and

a RF current generating means for generating RF current, wherein the RF current is supplied to the wire assembly arrangement through an electric conductor for contacting a pre-implanted stent, wherein the wire assembly arrangement and the pre-implanted stent forms an electrode arrangement for delivering RF current to a tissue for treating intravascular restenosis.

2. The medical device system as in claim 1, wherein the wire guide lumen is at one side of the wire guide shaft for rapid exchange of said medical device system over the guidewire.

3. The medical device system as in claim 1, wherein the wire guide lumen is connected to and in communication with the at least one lumen of the catheter shaft, and wherein the wire guide shaft is used for introducing said medical device system over the guidewire.

4. The medical device system as in claim 1 further comprising at least one temperature sensor, wherein the temperature sensor is disposed at close proximity of the wire assembly arrangement of the inner catheter.

5. The medical device system as in claim 4 further comprising a temperature controller, wherein temperature measured from the temperature sensor is relayed to the temperature controller and is adapted to effect the RF current supply to the medical device system.

6. The medical device system of claim 1, wherein the RP current is within the range of 50 to 2,000 kHz.

7. The medical device system of claim 1, wherein material for the preshaped expandable metallic basket members of the wire assembly arrangement is selected from the group consisting of platinum, iridium, gold, silver, stainless steel, Nitinol, and an alloy of their mixtures.

8. A method for treating intravascular restenosis of a patient having a pre-implanted stent, the method comprising delivering RF current to the pre-implanted stent through a medical device system comprising:

a flexible catheter shaft having a distal section, a shaft distal end, a shaft proximal end, and at least one lumen extending between the shaft proximal end and the shaft distal end, wherein the at least one lumen has at least one opening at the shaft distal end;

a handle attached to the shaft proximal end, wherein the handle has a cavity;

an inner catheter located inside the at least one lumen of the catheter shaft, wherein the inner catheter comprises a distal end and a proximal end;

a wire assembly arrangement mounted at the distal end of the inner catheter, wherein the wire assembly arrangement comprises a plurality of preshaped expandable metallic basket members, each metallic basket member having a member distal end, a member proximal end, wherein the member proximal ends of the preshaped expandable metallic basket members are joined at the distal end of the inner catheter and wherein the member distal ends of the preshaped expandable metallic basket members are joined at a distal joint;

a wire assembly deployment mechanism mounted on the handle, wherein the wire assembly deployment mechanism is coupled to the proximal end of the inner catheter, wherein the plurality of preshaped expandable metallic basket members are expanded at a deployed state, and wherein the plurality of preshaped expandable metallic basket members are retracted at a non-deployed state;

a wire guide shaft at the distal section of the catheter shaft, the wire guide shaft having a proximal end and a distal end that the wire guide shaft defines a wire guide lumen, wherein the wire guide lumen has at least one opening at the distal end and at least one opening at the proximal end of the wire guide shaft, wherein the wire guide shaft is used for introducing said medical device system into a vascular vessel over a guidewire; and

a RF current generating means for generating RF current, wherein the RF current is supplied to the wire assembly arrangement through an electric conductor for contacting the pre-implanted stent, wherein the wire assembly arrangement and the pre-implanted stent forms an electrode arrangement for delivering RF current to a tissue for treating intravascular restenosis.

9. A medical device system for delivering RF current to a pre-implanted stent comprising:

a flexible catheter shaft having a distal section, a shaft distal end, a shaft proximal end, and at least one lumen extending between the shaft proximal end and the shaft distal end, wherein the at least one lumen has at least one opening at the shaft distal end of the catheter shaft;

a handle attached to the shaft proximal end of the catheter shaft, wherein the handle has a cavity;

a wire assembly arrangement mounted at the distal section of the catheter shaft, wherein the wire assembly arrangement comprises a plurality of preshaped expandable metallic basket members, wherein at least a portion of the preshaped expandable metallic basket members is essentially straight or coiled adapted for contacting the pre-implanted stent, each metallic basket member having a member distal end, a member proximal end, wherein the member proximal ends of the preshaped expandable metallic basket members are joined at the distal end of the catheter shaft and wherein the member distal ends of the preshaped expandable metallic basket members are joined at a basket distal joint;

a wire assembly deployment mechanism mounted on the handle, wherein the wire assembly deployment mechanism comprises an elongated element inside the at least one lumen of the catheter shaft, wherein a distal end of We elongated element is secured to the basket distal joint, wherein the plurality of preshaped expandable metallic basket members is expanded at a deployed state, and wherein the plurality of preshaped expandable metallic basket members is retracted at a non-deployed state;

a wire guide shaft at the distal section of the catheter shaft, the wire guide shaft having a proximal end and a distal end that the wire guide shaft defines a wire guide lumen, wherein the wire guide lumen has at least one opening at the distal end and at least one opening at the proximal end of the wire guide shaft, wherein the wire guide shaft is used for introducing said medical device system into a vascular vessel over a guidewire; and

a RF current generator, wherein the RF current is supplied to the wire assembly arrangement through an electric conductor for contacting a pre-implanted stent, wherein the wire assembly arrangement and the pre-implanted stent forms an electrode arrangement for delivering RF current to a tissue for therapeutic purposes.

10. The medical device system as in claim **9**, wherein the plurality of preshaped expandable metallic basket members is expanded by pulling the elongated element toward the handle, and wherein the plurality of preshaped expandable metallic basket members is retracted by pushing the elongated element away from the handle.

11. The medical device system as in claim **9**, wherein the wire guide lumen is at one side of the wire guide shaft for rapid exchange of said medical device system over the guidewire.

12. The medical device system as in claim **9**, wherein the wire guide lumen is connected to and in communication with the at least one lumen of the catheter shaft, and wherein the wire guide shaft is used for introducing said medical device system over the guidewire.

13. The medical device system as in claim **9** further comprising at least one temperature sensor, wherein the temperature sensor is disposed at close proximity of the wire assembly arrangement of the catheter shaft.

14. The medical device system as in claim **13** further comprising a temperature controller, wherein temperature measured from the temperature sensor is relayed to the temperature controller and is adapted to effect the RF current supply to the medical device system.

15. The medical device system of claim **9**, wherein the RF current is within the range of 50 to 2,000 kHz.

16. The medical device system of claim **9**, wherein material for the preshaped expandable metallic basket members of the wire assembly arrangement is selected from the group consisting of platinum, iridium, gold, silver, stainless steel, Nitinol, and an alloy of their mixtures.

* * * * *

US006547760B1

(12) **United States Patent**
Samson et al.

(10) **Patent No.: US 6,547,760 B1**
(45) **Date of Patent: Apr. 15, 2003**

(54) **AORTIC CATHETER WITH POROUS AORTIC ARCH BALLOON AND METHODS FOR SELECTIVE AORTIC PERFUSION**

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(73) Assignee: **Cardeon Corporation**, Cupertino, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/366,188**

(22) Filed: **Aug. 3, 1999**

Related U.S. Application Data

(60) Provisional application No. 60/095,523, filed on Aug. 6, 1998.

(51) **Int. Cl.**[7] **A61M 31/00**; A61M 37/00; A61M 29/00

(52) **U.S. Cl.** **604/103.01**; 604/101.01; 604/606; 606/194

(58) **Field of Search** 604/96.01, 97.01, 604/98.01, 101.01, 101.05, 102.01–3, 103.06, 264, 523, 103.01, 103.07, 6.16, 915; 606/194, 192

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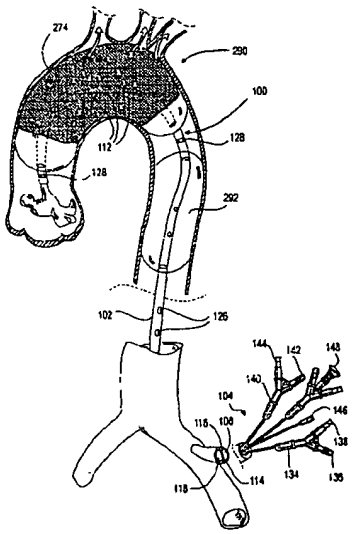
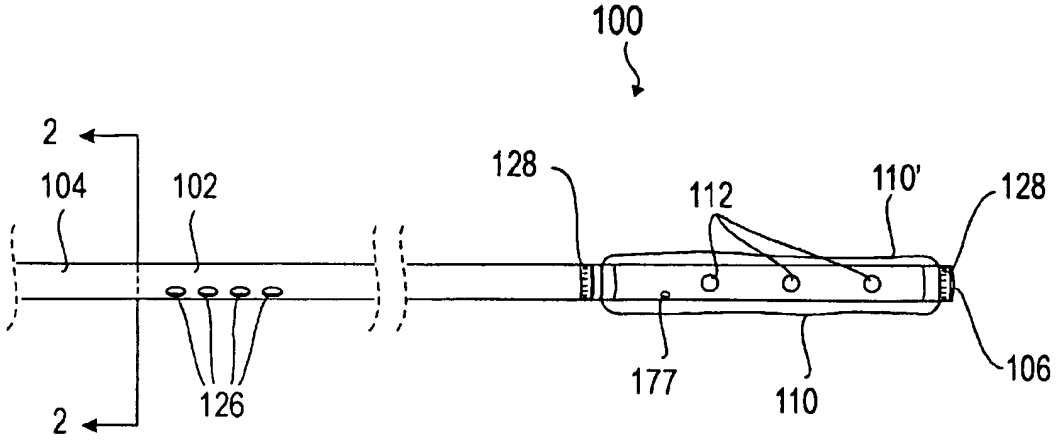
Primary Examiner—Brian L. Casler
Assistant Examiner—Catherine Serke
(74) *Attorney, Agent, or Firm*—Fulwider Patton Lee & Utecht, LLP

(57) **ABSTRACT**

A method and device for perfusing an organ system is provided. The device may be further described as a catheter or cannula with an expandable flow control member positioned of the distal portion of the catheter shaft. The flow control member has a porous portion, and at least one impermeable portion, which prevent fluid from flowing out the ends of the flow control member. The flow control member is further characterized as having an interior chamber that is in fluid communication with a perfusion lumen that extends along the length of the catheter shaft and is in fluid communication with an external perfusion pump. The perfusion lumen is configured for providing flow to the interior of the flow control member, to create radial expansion thereof and to provide adequate flow to the arch vessels through said porous portion to sustain the metabolic demands of the brain.

36 Claims, 13 Drawing Sheets

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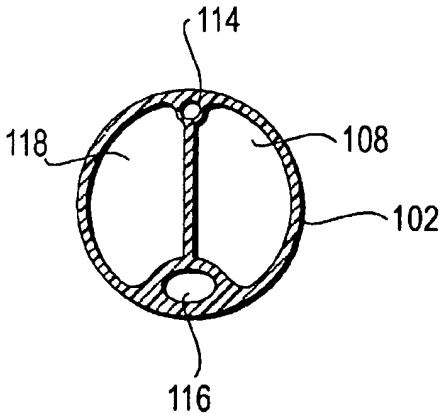
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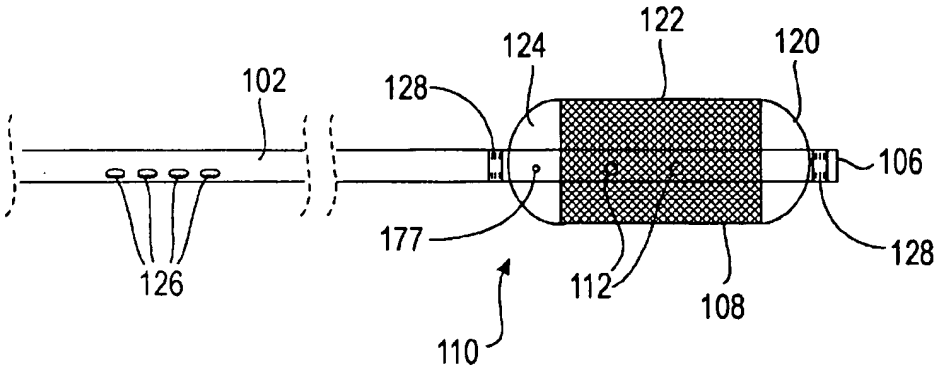
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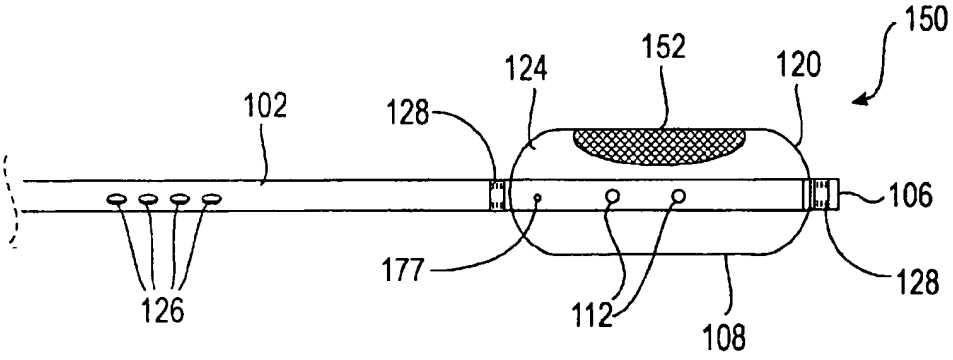
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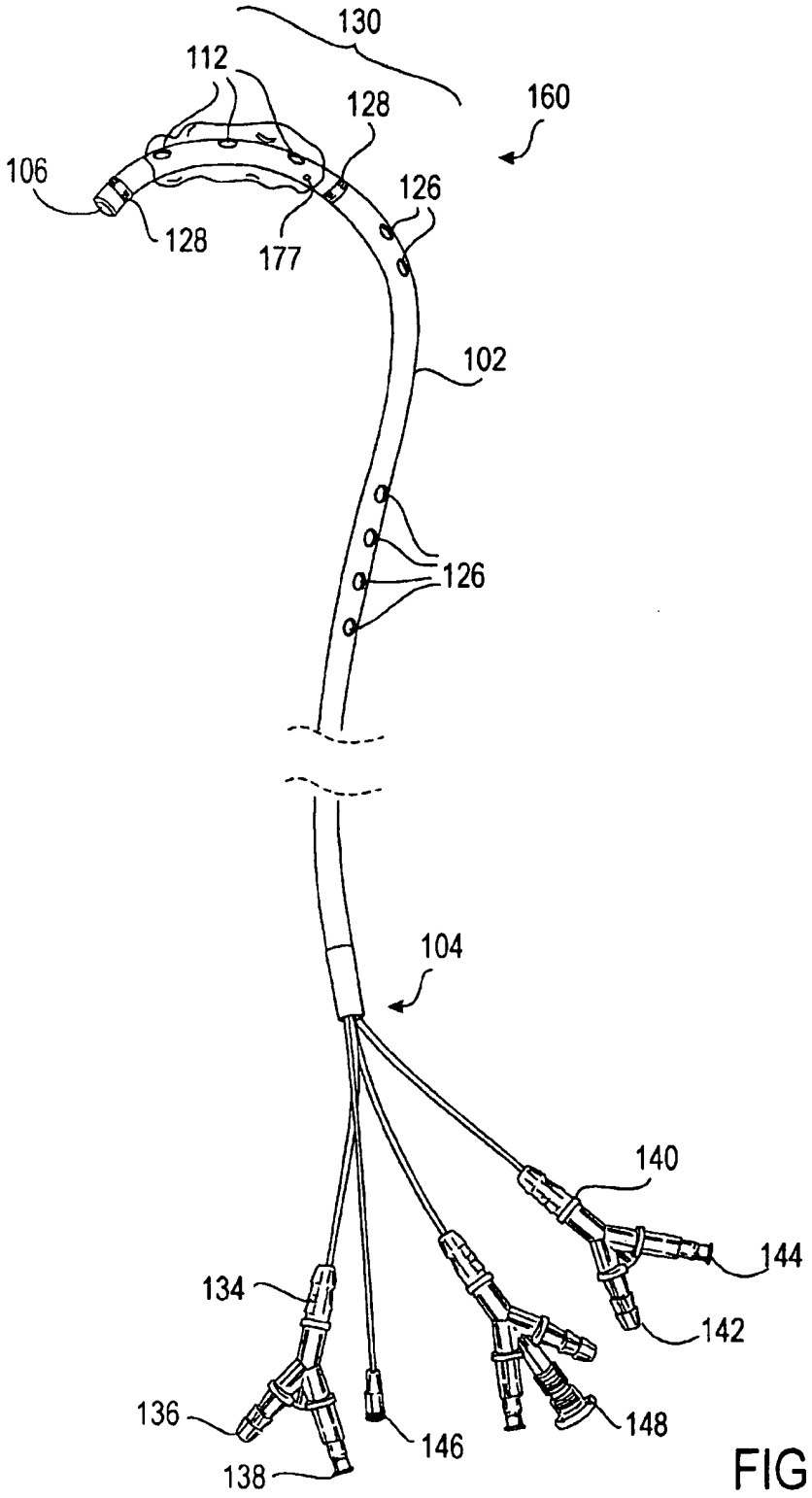
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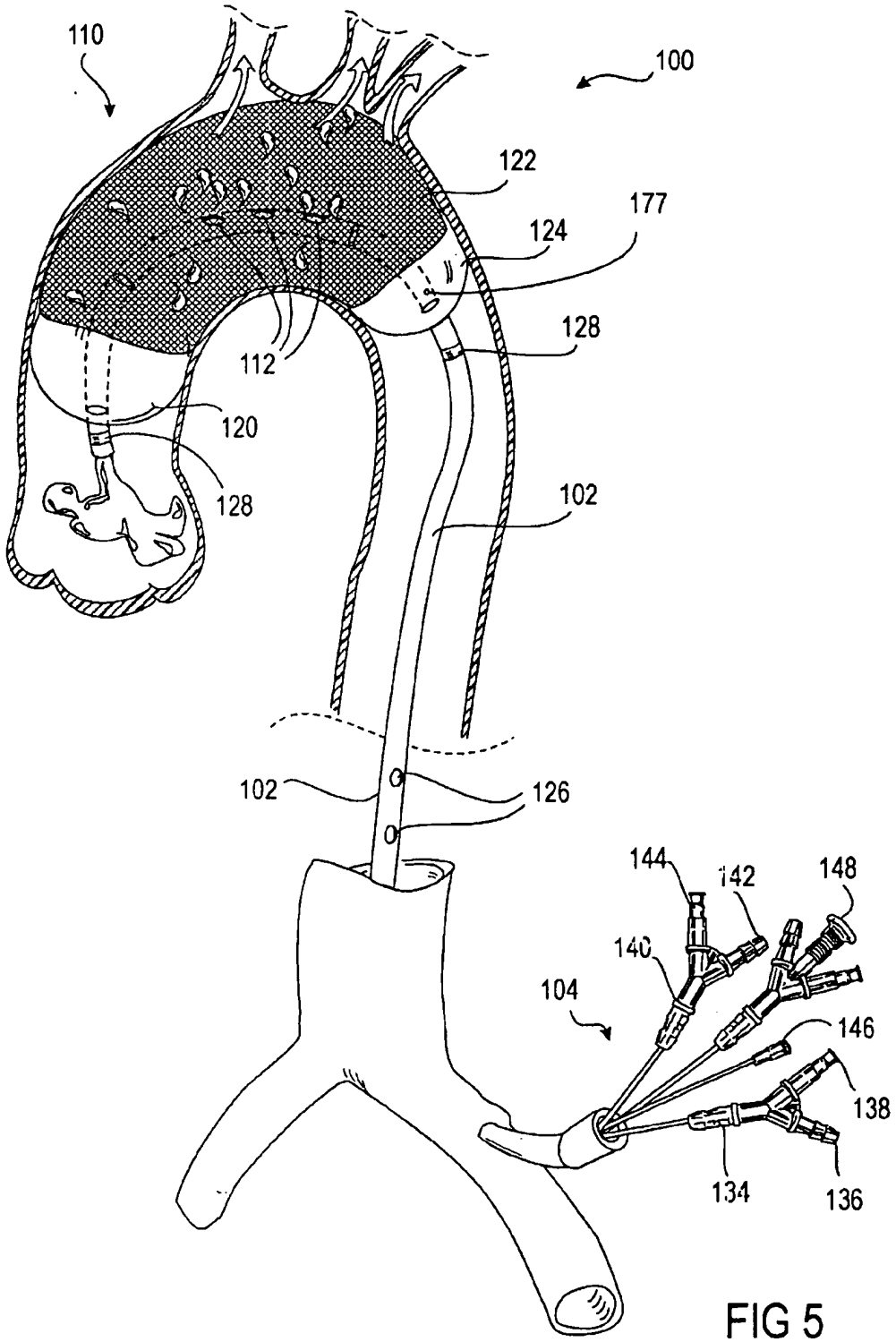
FIG 4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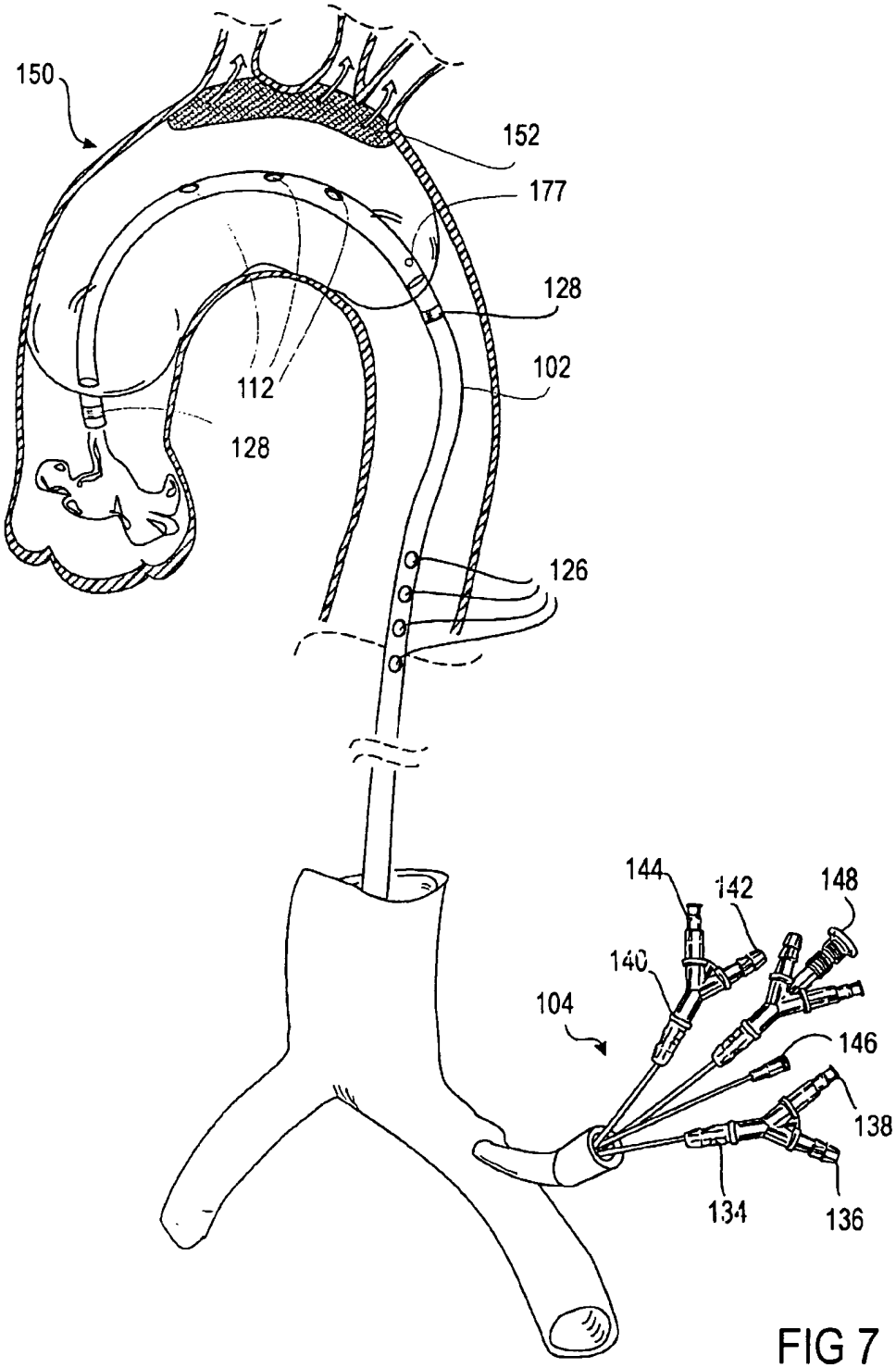
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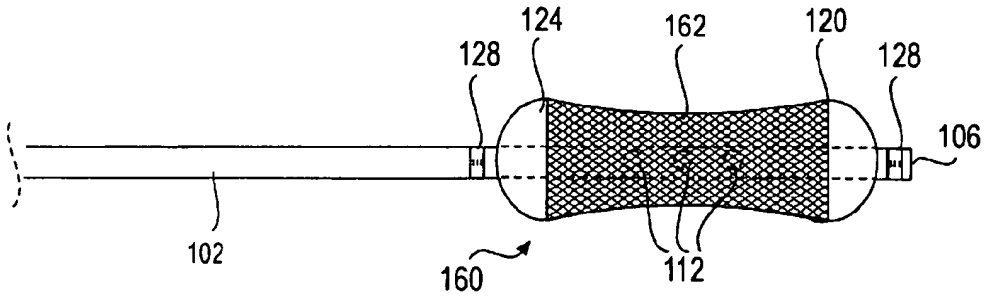

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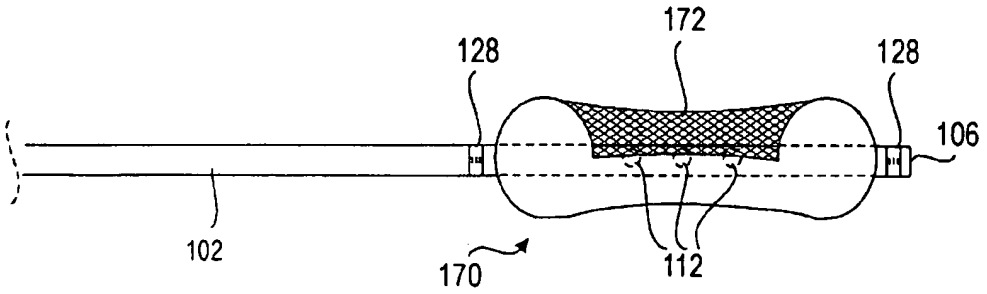

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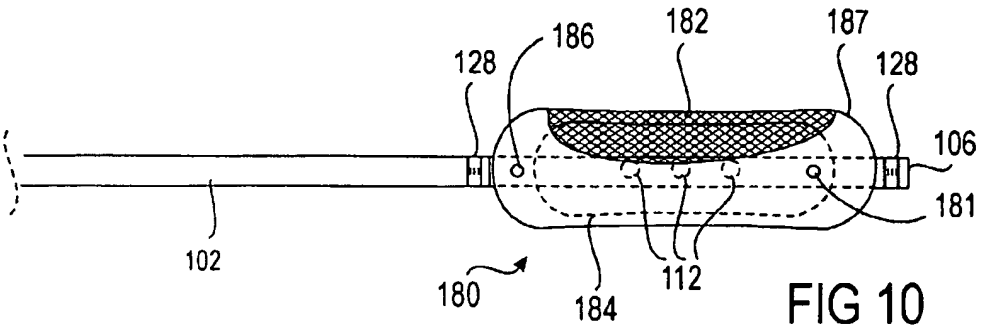

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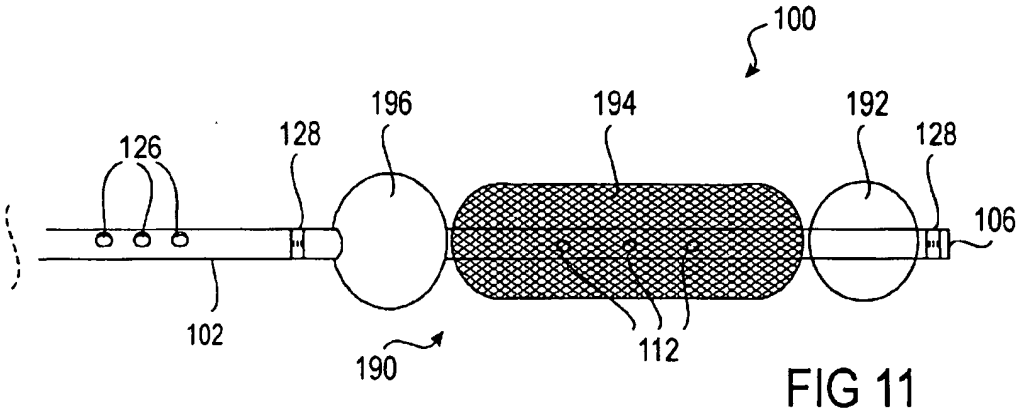

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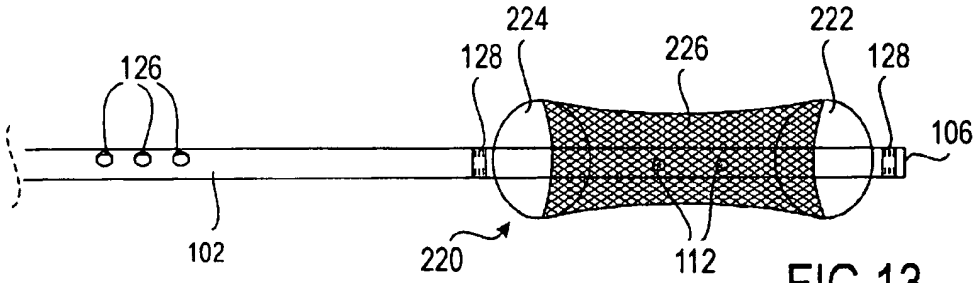

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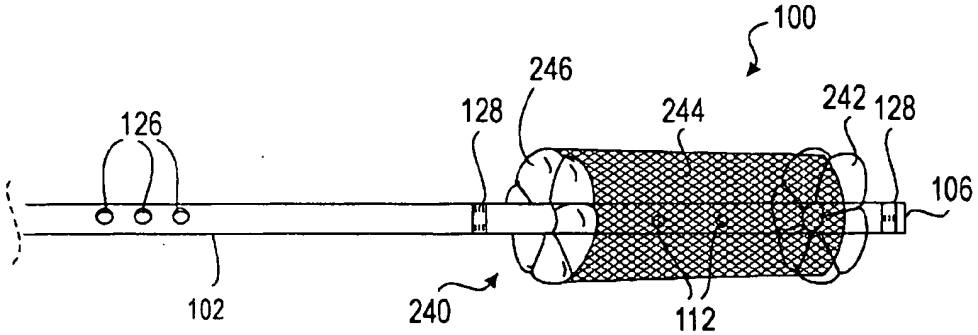


FIG 14

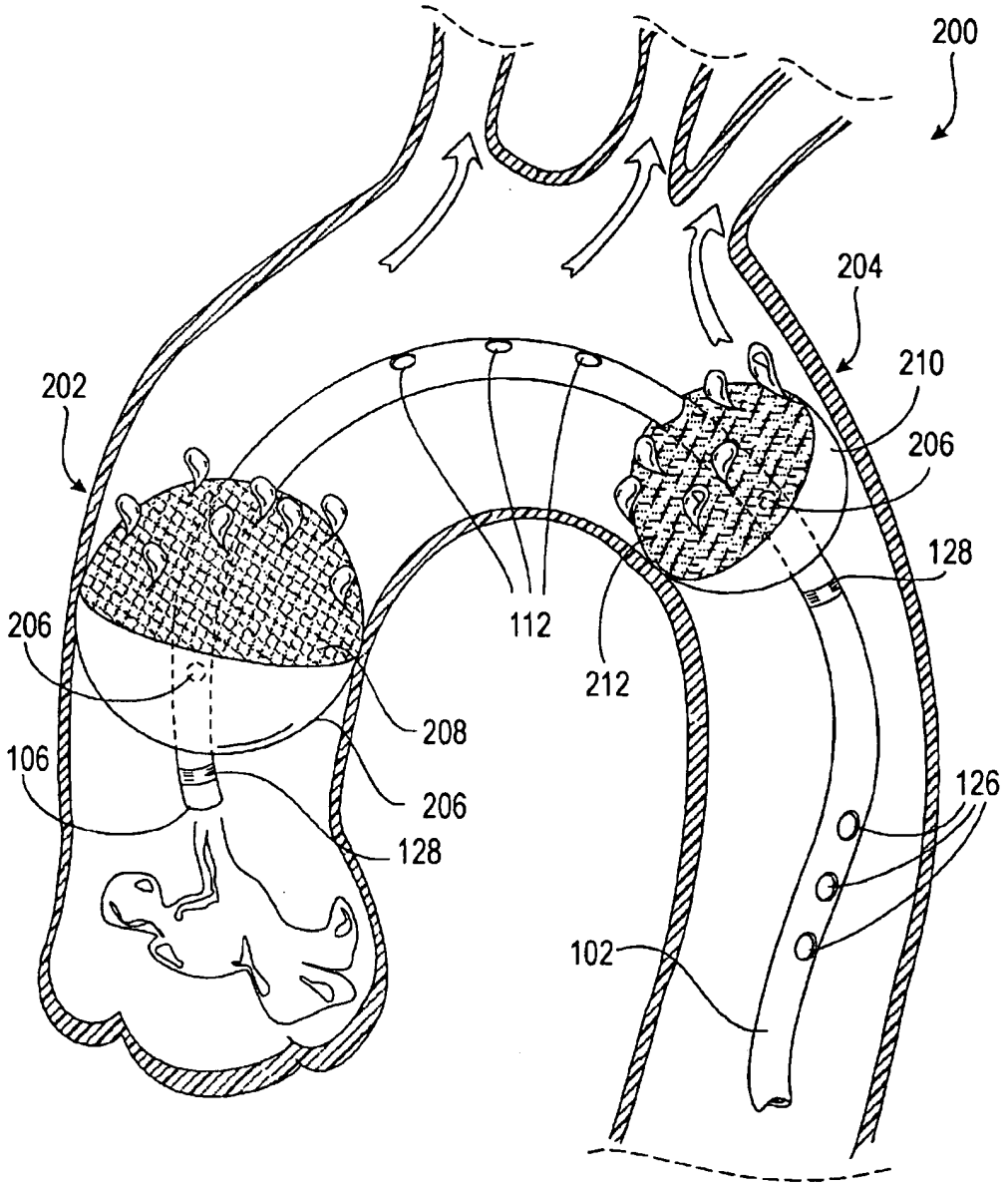
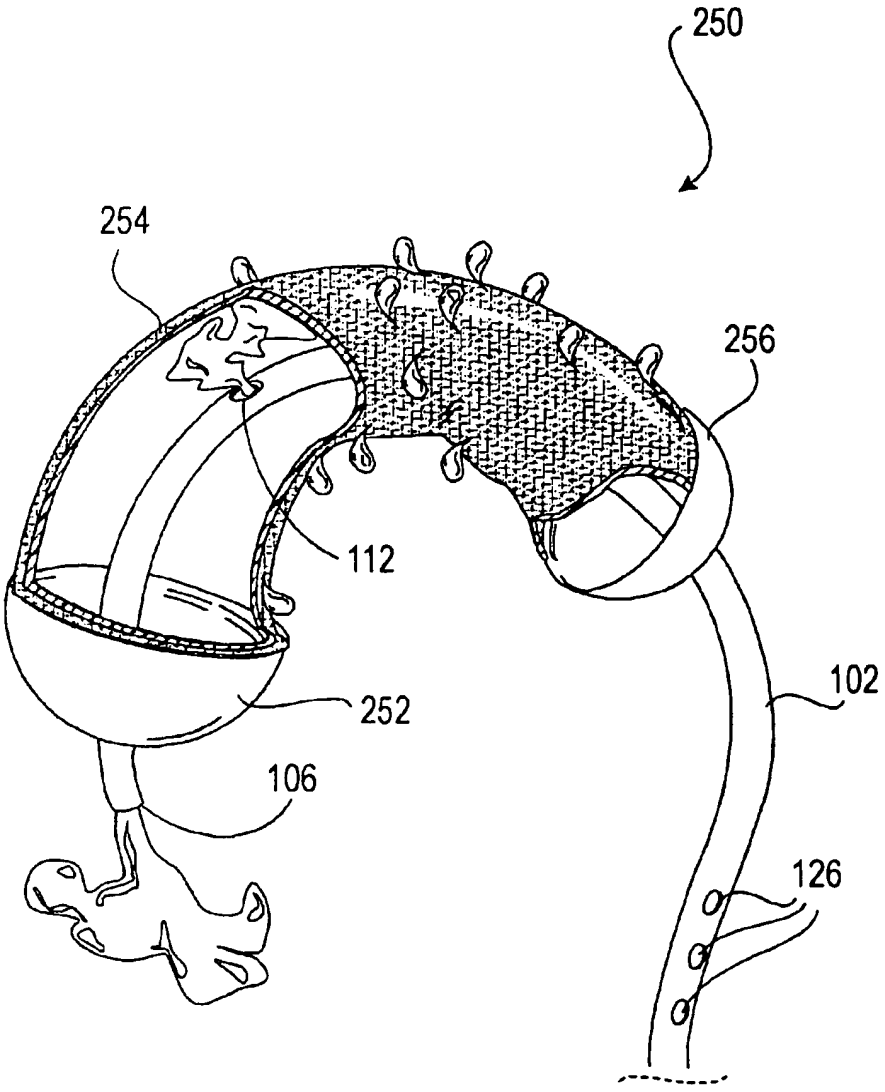


FIG 12



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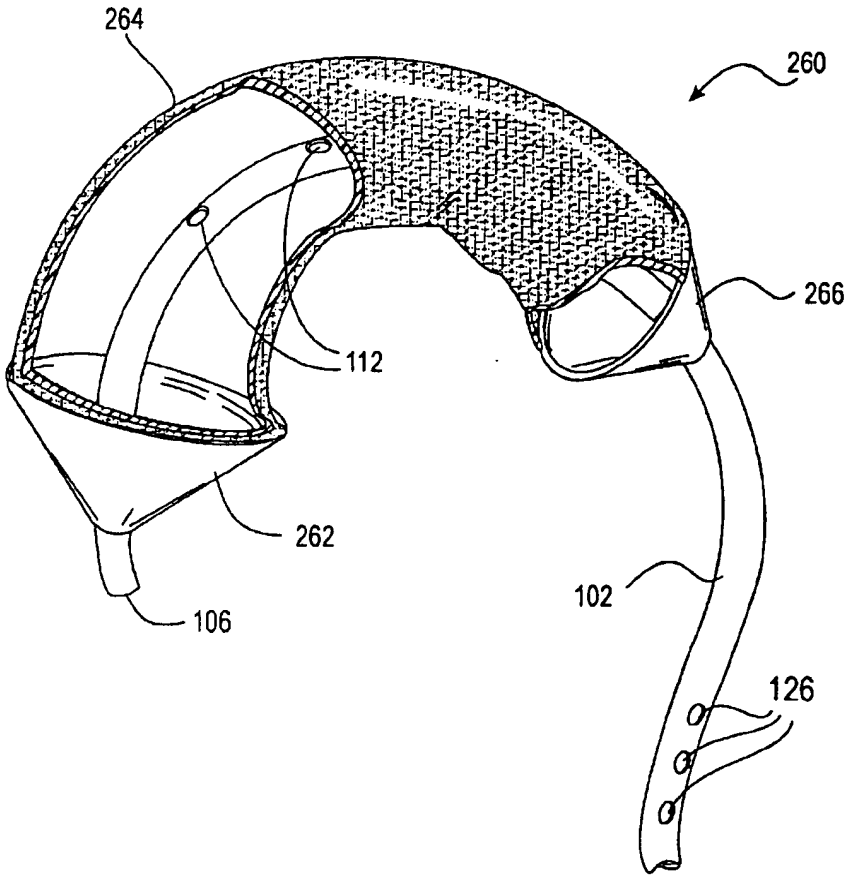

FIG 16

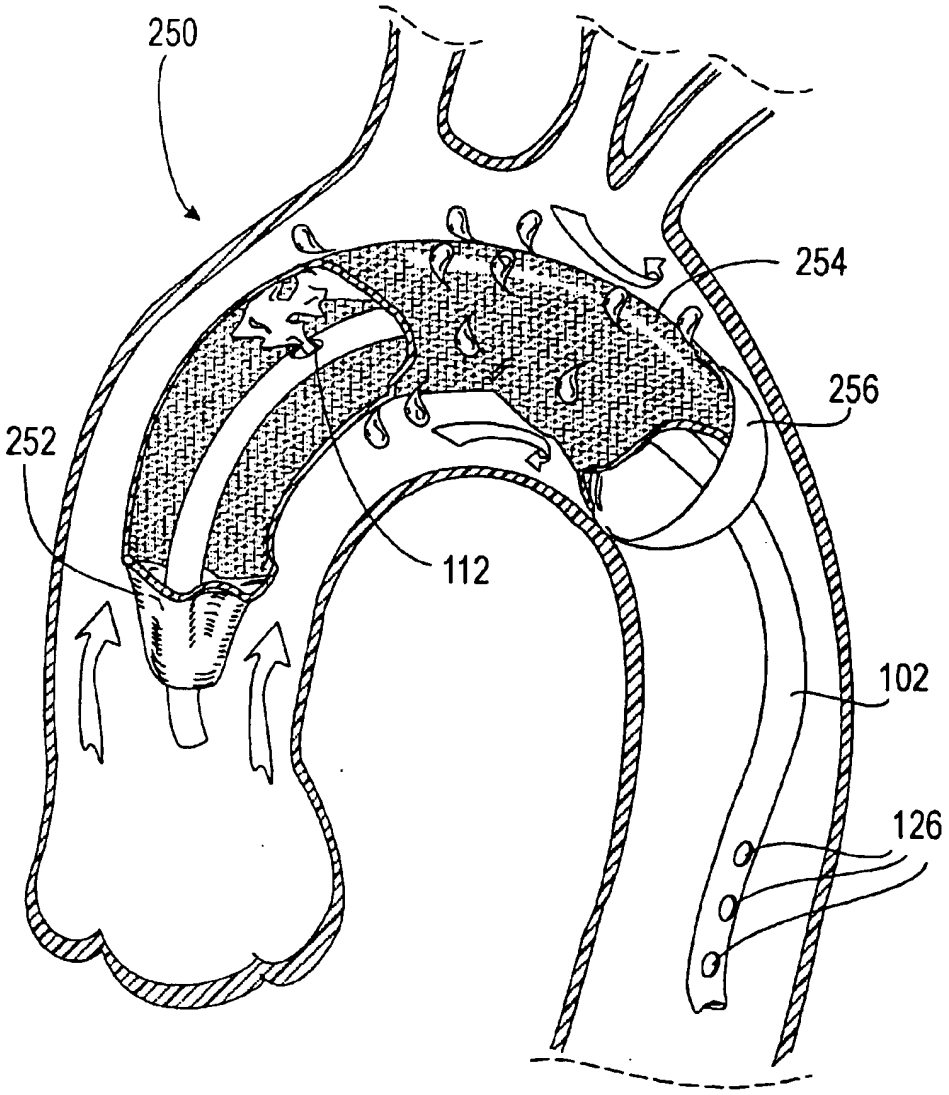

FIG 17

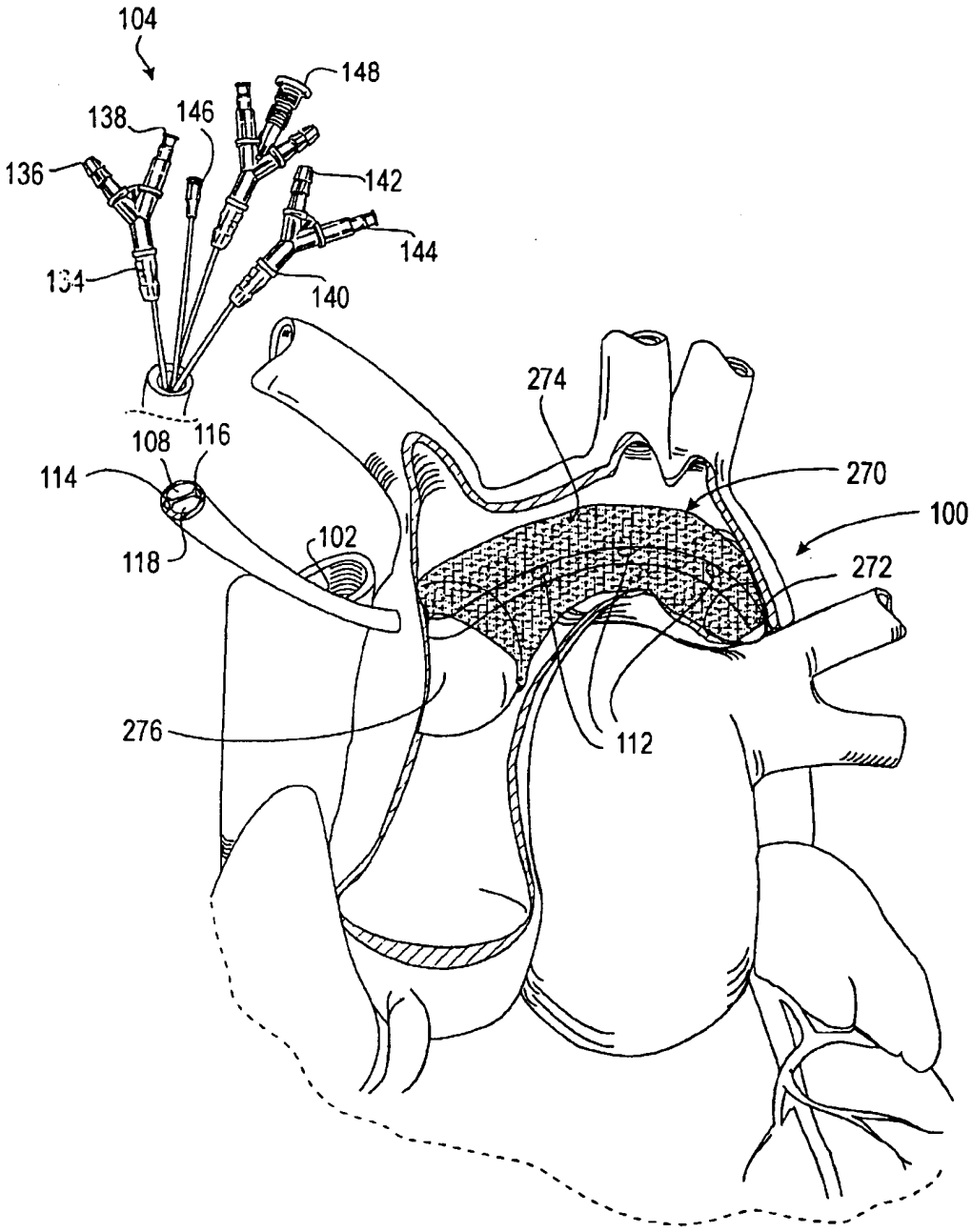
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FIG 18

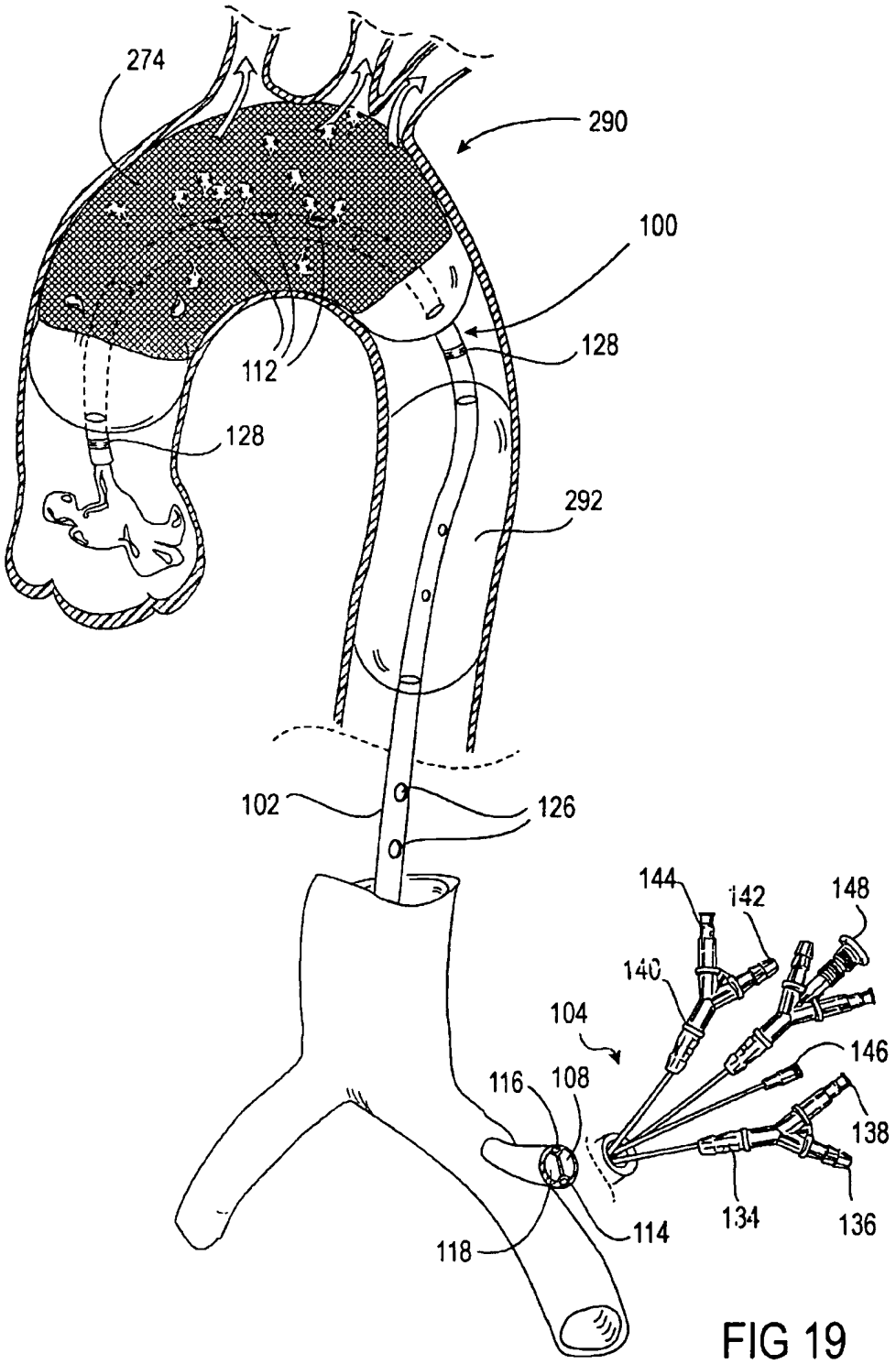
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FIG 19

AORTIC CATHETER WITH POROUS AORTIC ARCH BALLOON AND METHODS FOR SELECTIVE AORTIC PERFUSION

This application claims the benefit of Provisional application Ser. No. 60/095,523 filed Aug. 6, 1998.

FIELD OF THE INVENTION

The invention relates to a catheter or cannula system that facilitates cardiopulmonary surgeries and enables prolonged circulatory support of the heart. More specifically, the invention relates to an aortic catheter for segmenting and selectively perfusing the aorta during cardiopulmonary bypass.

BACKGROUND OF THE INVENTION

Heart surgery has generally required major open chest surgical procedures that put the patient at risk. Relatively high mortality rates and complications result from such invasive surgeries. Further, the surgeries require extensive hospitalization and recuperation time. Surgical methods to correct heart problems are desirable which do not require open chest approaches. Some surgical techniques have been described for particular applications employing an intra-aortic catheter introduced into the vascular system of the patient.

Recent advances in the field of minimally invasive cardiac surgery have included the development of aortic catheters and methods for inducing cardioplegic arrest without the necessity of opening the patient's chest with a sternotomy or other major thoracotomy. For example, U.S. Pat. No. Re 35,352 to Peters describes a single-balloon catheter for occluding a patient's ascending aorta and a method for inducing cardioplegic arrest. A perfusion lumen or a contralateral arterial cannula is provided for supplying oxygenated blood during cardiopulmonary bypass. U.S. Pat. No. 5,584,803 to Stevens et al. describes a single balloon catheter for inducing cardioplegic arrest and a system for providing cardiopulmonary support during closed chest cardiac surgery. A coaxial arterial cannula is provided for supplying oxygenated blood during cardiopulmonary bypass. The occlusion balloon of these catheters must be very carefully placed in the ascending aorta between the coronary arteries and the arch vessels, therefore the position of the catheter must be continuously monitored to avoid complications.

One difficulty encountered with prior art aortic catheters is the tendency of the single balloon catheters to migrate or drift in the direction of the pressure gradient within the aorta. Specifically, during infusion of cardioplegia, the balloon catheter will tend to drift downstream away from the heart and toward the aortic arch and, when the cardiopulmonary bypass pump is engaged during the procedure, the balloon catheter will tend to drift upstream in the opposite direction toward the heart into the aortic root. This migration can be problematic if the balloon drifts downstream far enough to occlude one or more of the arch vessels, or upstream enough to occlude the coronary arteries, or to pass through the aortic valve into the ventricle.

PCT patent application WO 9721462 by Fan et al. attempts to overcome this problem with a balloon catheter having high friction areas on the outer surface of the balloon. A problem with this single balloon approach is that a relatively large balloon is needed to create enough friction to avoid migration of the inflated balloon. The larger the balloon is, the more carefully it must be placed in the ascending aorta to avoid occluding the coronary arteries or the arch vessels and the less margin of error there is should any balloon migration occur.

Furthermore, what is needed are medical instruments and cannula/catheters for compartmentalizing and selectively perfusing the cerebral circulation with antegrade flow. Such mechanisms are necessary to minimize complications of a vast array that are related to proper management of blood flow in the body. Selective perfusion can be used to prioritize the flow of oxygenated blood or other protective fluids to the various organ systems, therefore achieving optimal preservation of all organ systems within the body.

Furthermore, what is needed is a peripheral access catheter configuration that is more resistant than prior apparatus to migration due to pressure gradients within the patient's aorta.

The following patents, and all other patents referred to herein, are hereby incorporated by reference in their entirety. U.S. Pat. Nos. 5,308,320, 5,383,854, 582,093 and 5,906,588 by Safar et al.; U.S. patent application Ser. No. 08/909,293, filed Jul. 11, 1997, by Safar et al.; U.S. patent application Ser. No. 09/152,589, filed Sep. 11, 1998, by Safar et al.; U.S. Pat. No. 5,738,649, by John A. Macoviak; U.S. patent application Ser. No. 09/060,412 filed Apr. 14, 1998 by Macoviak; U.S. Pat. Nos. 5,833,671, 5,827,237 by John A. Macoviak and Michael Ross; U.S. patent application Ser. No. 08/665,635, filed Jun. 17, 1996, by John A. Macoviak and Michael Ross; and U.S. patent application Ser. No. 09/205,753, filed Dec. 8, 1998, by Bresnahan et al.

SUMMARY OF THE INVENTION

Accordingly, the invention provides a catheter or cannula having a flow control member positioned near the distal end of the catheter for occluding a first body lumen at a point where a second body lumen branches from the first lumen, and for perfusing the branch lumen. The invention will be described more specifically herein relating to an aortic catheter or cannula having an occlusion member positioned in the aortic arch, having a length sufficient to cover the ostia of the arch vessels. The flow control member is intended to fulfill at least one and preferably all four of the following functions: (1) occluding the aorta at the aortic arch, (2) selectively perfusing one or more of the coronary arteries, the arch vessels, or the descending aorta with a selected fluid, (3) providing filtered perfusion to one or more of the coronary arteries, the arch vessels, or the descending aorta, and (4) resisting migration of the distal flow control member and the cannula.

The primary flow control member may be formed in a variety of configurations, but will include a primary flow control member positioned in the aortic lumen, having a length sufficient to cover the ostia of the arch vessels. The flow control member may comprise one or more inflatable balloons or one or more selectively deployable external catheter valves, or a combination of balloons and valves. In embodiments where the primary flow control member is a single inflatable balloon, the flow control member will have at least one permeable or mesh portion. The balloons used, whether porous or nonporous, may be elastic so that they stretch in proportion to the inflation pressure, or may be flaccid or sack-like so that they inflate at low pressure and reach their design diameter quickly. The sack-like balloons may be relatively non-compliant at their design diameter or they may be compliant, exhibiting elastic behavior after initial inflation, e.g. to closely fit the aortic lumen size and curvature.

The catheter may further include one or more auxiliary flow control members located upstream or downstream from the primary flow control member to further segment the

patient's circulatory system for selective perfusion to different organ systems or to assist in anchoring the catheter in a desired position. Usable auxiliary flow control members include, but are not limited to, expandable or inflatable members such as inflatable balloons and valves. Examples of various valves may include collapsible/expandable valves including retrograde valves, antegrade valves, and various central flow and peripheral flow valves. In addition, a combination of valves and inflatable members may be used as appropriate for a given procedure. In some embodiments, the catheter body can include one or more antegrade and retrograde valves, as well as one or more inflatable balloons. Inflatable balloons and collapsible/deployable valves have been previously incorporated by reference herein and any desirable or practical inflatable balloon or deployable valve may be used. Inflatable balloons typically include an interior chamber that is in fluid communication with an inflation lumen extending within the catheter shaft from a location from within the respective flow control member to a location in the proximal portion, which is adapted to extend out of the patient.

Preferably, the flow control member, and any auxiliary flow control members, or anchoring members, if present, are mounted on an elongated catheter shaft. In a preferred embodiment, the catheter shaft includes at least one lumen for inflating or otherwise deploying the primary flow control member and for perfusion of the arch vessels with oxygenated blood or other fluids, a lumen for corporeal perfusion, and a guidewire lumen. In alternate embodiments, lumens may be included for deploying the auxiliary flow control members, and for measuring the pressure at desired locations within the aorta. The catheter may be configured for retrograde deployment via a peripheral artery, such as the femoral artery, or it may be configured for antegrade deployment via an aortotomy incision or direct puncture in the ascending aorta.

In some embodiments of the invention, filtration may be an important feature. To capture embolic material without unduly disrupting blood flow, the porous section or sections must have an appropriate combination of characteristics including effective filter surface area and pore size;

the correct combination depending on a number of factors including fluid pressure. For filters comprised of a mesh, the thread diameter is another important characteristic to consider. Typically, the flow rates required in the arch vessels total between 0.5 and 1.5 L/min depending on a variety of factors including the size of the patient and the temperature of the perfusate. Pore size is preferably 500 μm or less, more preferably 200 μm or less, and most preferably 50 μm or less, but larger than at least a red blood cell, although larger pore sizes may be required in some embodiments.

Methods according to the present invention are described using the aortic catheter for occluding and compartmentalizing or partitioning the patient's aortic lumen and for performing selective filtered aortic perfusion.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side view of a shaft portion of a first embodiment of the aortic catheter of the present invention having a single-balloon flow control member in the unexpanded state.

FIG. **2** is a magnified lateral cross section of the aortic catheter shaft of FIG. **1** taken along line **2**—**2**.

FIG. **3** is a side view of the flow control member of the aortic catheter of FIG. **1** showing a single-balloon flow control member in a deployed or expanded state.

FIG. **4** is a side view of the aortic catheter of FIG. **1** configured for retrograde introduction into a patient's femoral artery and illustrating the manifold connections to the proximal end of the aortic catheter.

FIG. **5** is a side view of the aortic catheter of FIG. **1** deployed or expanded in an aorta.

FIG. **6** is a side view of a shaft portion of a second embodiment of an expanded or deployed single-balloon flow control member with a porous window.

FIG. **7** is a side view of the aortic catheter of FIG. **6** deployed or expanded in the aorta of a patient, showing the porous window aligned with the ostia of the arch vessels.

FIG. **8** is a side view of a third alternate embodiment of the primary flow control member of the present invention wherein the porous middle portion of the primary flow control member has a deployed diameter less than the deployed diameter of the proximal and distal ends.

FIG. **9** is a side view of an alternate embodiment of the primary flow control member of the invention with a porous window, where the middle portion of the flow control member has a deployed diameter less than the deployed diameter of the proximal and distal ends of the flow control member.

FIG. **10** is a side view of an embodiment where the flow control member of the invention comprises an inner balloon and an outer balloon.

FIG. **11** is a side view of an embodiment of the primary flow control member wherein the primary flow control member is a compound structure comprised of three flow control elements.

FIG. **12** is a side view of another embodiment of the primary flow control member wherein the primary flow control member is a compound structure comprised of two flow control elements deployed in a patients aorta.

FIG. **13** is a side view of an embodiment of the primary flow control member wherein the primary flow control member is a compound structure comprised of three flow control elements with a filter mesh coupled to and deployed between them.

FIG. **14** is a side view of another embodiment of the primary flow control member wherein the primary flow control member is a compound structure comprised of two valve flow control elements and one porous inflatable balloon flow control member.

FIG. **15** is a side view of another embodiment of the primary flow control member wherein the primary flow control member is a compound structure comprised of two end cap valve flow control elements and one porous inflatable balloon flow control element partially received within each valve element.

FIG. **16** is a side view of an embodiment of the primary flow control member similar to that shown in FIG. **15**, except the valve elements are conical.

FIG. **17** is a side view of the embodiment of the primary flow control member similar to that shown in FIG. **15** deployed within a patient's aortic arch, and showing the distal valve element partially collapsed.

FIG. **18** is a side view of an embodiment of the primary flow control member of the invention configured for antegrade deployment.

FIG. **19** is a side view of an embodiment the catheter of the invention further comprising an auxiliary flow control member positioned in the patient's descending aorta.

DETAILED DESCRIPTION OF THE INVENTION

Turning now descriptively to the drawings, in which similar reference characters denote similar elements

throughout the separate embodiments, the catheter described herein with all of its preferred features represents a versatile device having multiple uses. The invention provides a catheter having a primary flow control member positioned near the distal end of the catheter for occluding a first body lumen at a point where a second body lumen branches from the first body lumen and for perfusing the branch lumen. However, the invention will be described more specifically herein relating to an aortic catheter having a primary flow control member configured to be positioned in the aortic arch and having a length sufficient to cover the ostia of the arch vessels. The primary flow control member may have at least one permeable or mesh portion in fluid communication with the ostia of the arch vessels, and may be an inflatable balloon, or include one or more inflatable balloons, or one or more selectively deployable external catheter valves as subunits thereof, or a combination of balloons and valves as subunits thereof. The catheter is characterized by a flexible catheter shaft placed by surgical cutdown or needle/introducer guidewire technique into the vessels of the lower or upper extremity or neck. Larger internal vessels may also be used. Alternatively, the catheter may be introduced centrally through direct penetration of the ascending aorta.

In some embodiments, filtration may be an important feature of the invention. To filter blood and effectively capture embolic material without unduly disrupting blood flow, the porous section or sections must include an appropriate combination of characteristics including effective filter surface area and pore size, which combination will vary depending on a number of factors including the fluid pressure inside the catheter. For filters comprised of a mesh, the thread diameter is another important characteristic to consider. Typically, the flow rates required in the arch vessels total between 0.5 and 1.5 L/min depending on a variety of factors including the size of the patient and the temperature of the perfusate. Pore size is preferably 500 μm or less, more preferably 200 μm or less, and most preferably 50 μm or less, but larger than at least a red blood cell. However, small filter surface areas disclosed in some embodiments may require larger pore sizes than those given above in order to achieve the necessary rate of flow at an acceptable pressure.

Once appropriate physical characteristics are determined, suitable meshes can be found among standard meshes known in the art. For example, polyester meshes may be used, such as meshes made by Saati Corporations and Tetko, Inc. These are available in sheet form and can be easily cut and formed into a desired shape. Other meshes known in the art, which have the desired characteristics are also suitable.

Anticoagulants or antithrombogenic compounds may be applied to the mesh to reduce the chances of blood clotting on the mesh. The anticoagulants or antithrombogenic compounds may be painted, dipped, sprayed or chemically bonded onto the mesh and/or onto other parts of the catheter or the catheter lumens. Other methods known in the art for applying anticoagulants or antithrombogenic compounds may also be used. Anticoagulants, such as heparin and heparinoids, may be used. Anticoagulants other than heparinoids may also be used, for example monoclonal antibodies such as ReoPro.

Perfusion of blood to the arch vessels will preferably be performed with a pressure drop through the catheter and across the filter of less than approximately 300 mm Hg, more preferably less than approximately 100 mm Hg, in order to reduce hemolysis while providing a blood flow preferably between 0.5 to 1.5 liters per minute. Preferred perfusion pressures may be different for perfusates that do not contain blood and therefore are not subject to hemolysis.

FIG. **1** illustrates the shaft portion of a first embodiment of the invention having a primary flow control member **110**. FIG. **2** is a magnified lateral cross section of the aortic catheter taken along line **2**—**2** in FIG. **1**. The aortic catheter **100** has an elongated catheter shaft **102** having a proximal portion **104** that preferably extends out of the patient's body, and a distal end **106** adapted to extend into the patient's aorta. The elongated catheter shaft **102** should have an overall length sufficient to reach from the arterial access point where it is inserted into the patient to its deployed position within the aorta. For femoral artery deployment in adult human patients, the elongated catheter shaft **102** preferably has an overall length from approximately 60 cm to 120 cm, and more preferably 70 cm to 90 cm.

Referring to FIG. **2**, which is a cross section of the catheter shaft **102** taken along line **2**—**2** of FIG. **1**, the elongated catheter shaft **102** preferably has at least four lumens, an inflation/perfusion lumen **108** that provides blood to the primary flow control member **110** and to the arch vessels through the flow control member perfusion ports **112**, a pressure lumen **114** opens to a pressure port **177**, a guidewire lumen **116**, and a corporeal perfusion lumen **118** that is used to perfuse the descending aorta through the corporeal perfusion ports **126**. The configuration of the lumens shown is for illustrative purposes only, and other configurations may be used. For example, in alternate embodiments the catheter shaft **102** may not include a corporeal perfusion lumen **118** or pressure lumen **114** that will help simplify the manufacture of the aortic catheter **100**. In configurations where corporeal perfusion is not integrally built into the aortic catheter, corporeal perfusion may be provided by a coaxial, collateral or contralateral arterial cannula. Alternatively, additional lumens may be included such as perfusion lumens, monitoring lumens or validation of catheter placement lumens.

In a preferred embodiment, the elongated catheter shaft **102** has an outer diameter that is preferably approximately 9 to 26 French (3.0 to 8.7 mm), and more preferably 12 to 18 French (4.0 to 6.0 mm) for use in adult human patients. Catheters for pediatric use, or use in non-human subjects, may require different dimensions and would be scaled accordingly. The elongated catheter shaft **102** is preferably formed of a flexible thermoplastic material, a thermoplastic elastomer, or a thermoset elastomer. Suitable materials for use in the elongated catheter include, but are not limited to, polyvinylchloride, polyurethane, polyethylene, polyamides, polyesters, silicone, latex, and alloys or copolymers thereof, as well as braided, coiled or counterwound wire or filament reinforced composites.

The primary flow control member **110**, of FIG. **1**, is mounted proximal the distal end **106** of the elongated catheter shaft **102** or alternatively may extend beyond the distal end **106**. The flow control member **110** is intended to fulfill at least one and preferably all four of the following functions: (1) occluding the aorta at the aortic arch, (2) selectively perfusing one or more of the coronary arteries, the arch vessels, or the descending aorta with a selected fluid, (3) providing filtered perfusion to one or more of the coronary arteries, the arch vessels, or the descending aorta, and (4) resisting migration of the primary flow control member **110** or cannula **100**.

FIG. **3** illustrates the flow control member **110** of FIG. **1** in the expanded or deployed position. The expandable flow control member may be mounted to the exterior of the catheter shaft by heat bonding, heat welding, with an adhesive or by mechanical or frictional means. The flow control member **110** comprises a balloon having a distal end **120**, a

middle portion **122**, and a proximal end **124**. The distal end **120** and the proximal end **124** are preferably formed of a nonporous material creating at least one occlusive end, while the middle portion is preferably formed of a mesh or porous material. The inflatable flow control member **110** has a deflated state **110'** as illustrated with reference to FIG. **1**, in which the diameter of the flow control member is, preferably, not substantially larger than the diameter of the catheter shaft **102** and an inflated state **108** in which the flow control member **110** expands to a diameter sufficient to at least partially occlude blood flow in the aortic arch of a patient. For use in adult humans, the flow control member **110** preferably has an inflated outer diameter of approximately 1 to 7 cm more preferable 2 to 5 cm. When the primary flow control member **110** comprises an inflatable balloon, whether porous or nonporous, the inflatable balloon may be elastic so that it stretches in proportion to the inflation pressure, or may be flaccid or sack-like so that it inflates at low pressure and reaches its design diameter quickly. The sack-like balloon may be relatively non-compliant at its design diameter or it may be compliant, exhibiting elastic behavior after initial inflation, to closely fit the aortic lumen size and curvature. The material or materials used in the inflatable primary flow control member **110** is preferably characterized by properties that allow an internal pressure within the distal flow control member **110** to be maintained at a sufficient level to occlude the aorta, while also allowing a controlled volume of fluid to escape from the flow control member for perfusing the arch vessels. Suitable materials which may be used for flow control member **110** include polyurethanes, polyethylene terephthalate (PET), polyvinyl chloride (PVC), ethylene vinyl acetate (EVA), latex and polyolefin. Furthermore, the surface of the flow control member may have porous regions that allow a fluid to be perfused at a known rate when a specific pressure is attained while not allowing other porous regions to open until a greater internal pressure in the balloon is attained. For perfusion of the arch vessels, it is preferable that the flow rate provided to the arch vessels be controllable within a range from 0.1 to 2.0 liters per minute, and more preferably within a range from 0.5 to 1.5 liters per minute, depending on a variety of factors. Therefore, the flow control member **110** has material properties that allow for the aforementioned perfusion range while still maintaining occlusion properties when deployed in the aorta.

The porous and nonporous sections of the primary flow control member **110** may be formed from the same or separate materials. Suitable materials for the nonporous portions of the inflatable flow control member **110** include, but are not limited to, elastomers, thermoplastic elastomers, polyvinylchloride, polyurethane, polyethylene, polyamides, polyesters, silicone, latex, and alloys or copolymers, and reinforced composites thereof. In addition, the outer surface of the flow control member **110** may include a force or friction increasing means such as a friction increasing coating or texture to increase friction between the distal flow control member **110** and the aortic wall when deployed. Suitable materials for the mesh or porous middle portion **122** include, but are not limited to, a perforated polymer film, porous or microporous membranes, TYVEK (spun-bonded polyethylene), GORTEX (expanded PTFE), woven or knit mesh or fabric, or the like.

Referring now to FIG. **4**, to facilitate placement of the catheter **100** within the aorta, and to improve the stability of the catheter **100** in the proper position in the patient's aorta, a distal region **130** of the aortic catheter **100** may be preshaped to conform to the internal curvature of the patient's aortic arch. The distal region **130** represents a J-shaped curve of approximately 180 degrees of arc with a radius of curvature of approximately 2 to 4 centimeters, for use in a typical adult human patient and may be reinforced with polymer filaments or metal or both. The distal end **106** of the aortic catheter **100** may also be skewed slightly out of the plane reflecting the forward angulation of the typical patient's ascending aorta.

The proximal end/portion **104** of the aortic catheter **100** has fittings for each of the catheter lumens **108**, **114**, **116**, and **118**. The corporeal perfusion lumen **118** is coupled to a Y-fitting **134** having a barb connector **136** for connection to a perfusion pump or the like, and a luer connector **138** for injecting medications or other fluids. In alternate embodiments, the catheter shaft **102** may further include a pressure lumen coupled to a luer connector for monitoring the corporeal perfusion pressure, withdrawing fluid samples, or for injecting medications or other fluids. The flow control member deployment and perfusion lumen **108** is coupled to a Y-fitting **140** having a barb connector **142** for connection to the same perfusion pump **900** a perfusion pump or the like, and a luer connector **144** for injecting medications or other fluids. The arch pressure lumen **114** is coupled to a luer connector **146** for monitoring the arch perfusion pressure, withdrawing fluid samples, or for injecting medications or other fluids. The guidewire lumen **116** is coupled to a Touhy-Borst fitting **148**, or other hemostasis valve. In alternate embodiments having an auxiliary flow control member and where separate lumens are desired for deploying the auxiliary flow control member, additional fittings suitable for connecting to a syringe or other inflation or deployment device would be provided.

Illustrated in FIG. **5** is the flow control member **110** deployed in the aorta illustrating the functional features and material attributes of the control member **110** in use. The flow control member **110** is positioned within the aortic arch with the porous middle portion **122** covering the ostia of the arch vessels. A selected fluid, such as oxygenated normothermic blood, oxygenated hypothermic blood, blood substitutes such as PERFLUBRON or other perfluorocarbon compounds, radiopaque dyes for angiography, or the like, is introduced through the flow control member inflation and perfusion lumen **108** into the inflatable flow control member **110**. Some selected fluid may seep out through the porous middle portion **122** during inflation, but at a rate less than the rate at which the selected fluid enters the flow control member **110**. In an alternate embodiment, it may be preferable to initially inflate the flow control member **110** with a more viscous solution, for example a radiopaque contrast agent mixed with saline, that will flow through the porous middle portion **122** at a rate slower than the selected perfusion fluid will leak.

When the correct pressure is attained, the flow control member **110** occludes blood flow through the aortic lumen. The selected fluid used to inflate the flow control member **110** may escape through the porous portion **122** at a known rate into the arch vessels. The flow rate may be adjustable by adjusting the pressure within the flow control member **110**. Contact with the aortic wall and the middle porous portion **122** of the flow control member **110** will reduce or prevent seepage of the selected fluid through sections of the porous middle portion **122** of the flow control member **110** not aligned with the arch vessels. The middle porous portion **122** of the flow control member **110** contacting the aortic wall may also provided resistance to the migration of the flow control member **110** or cannula **100**.

Preferably, the aortic catheter **100** includes one or more location markers **128**, such as radiopaque markers and/or

sonoreflective markers, to enhance imaging of the aortic catheter **100** during deployment using standard fluoroscopy, ultrasound, MRI, MRA, transesophageal chocardiography, or other techniques. A radiopaque location marker **128** may be formed as a ring or disk of dense radiopaque metal such as gold, platinum, tantalum, tungsten, or compounds or alloys thereof, or a ring of a polymer or adhesive material heavily loaded with a radiopaque filler material.

In use, the catheter **100** is advanced up the descending aorta and across the aortic arch, under fluoroscopic or ultrasound guidance with the aid of a guidewire within the guidewire lumen **116**. The aortic catheter **100** is advanced until the primary flow control member **110** is positioned in the aortic arch. This may be determined by reference to the radiopaque marker or markers **128**. Using a multihead cardiopulmonary bypass pump or the like, perfusion of oxygenated blood is started through the perfusion ports **112**. The flow control member **110** is then inflated to occlude the aortic arch using a selected perfusion fluid such as oxygenated blood. When the correct pressure is achieved, the perfusion fluid flows from the flow control member **110** and enters the arch vessels. The rate of flow of the perfusion fluid may be controlled by adjusting the pressure within the flow control member **110**. At the completion of the surgical procedure, the flow control member **110** is allowed to deflate, allowing oxygenated blood to flow from the heart to the arch vessels, the descending aorta, and to the coronary arteries. The heart should then spontaneously resume normal sinus rhythm, however, if necessary, cardioversion or defibrillation shocks may be applied to restart the heart. The patient is then weaned off the bypass and the aortic catheter, and other cannulas, are withdrawn. The alternate embodiment configured for antegrade deployment would be used similarly, except that access to the patient's circulatory system would be made through a central access by an aortotomy or incision directly into the ascending aorta.

Modification of the operational characteristics or procedures set forth above for use in vessels other than the aorta for perfusion of blood to branch vessels are readily ascertainable by those skilled in the art in view of the present disclosure.

In an alternate embodiment seen in FIGS. **6** and **7**, the flow control member **150** comprises a nonporous balloon with a porous window **152**. In this variation, the catheter **100** may be made of the same materials as those described in relation to the catheter **100** of FIGS. **1** through **5**. Common numbers refer to common assembly components, therefore the description of these parts as explained in connection with FIGS. **1** through **4** is incorporated by reference into this illustrative embodiment and all others to follow. The relative position, size and shape of the porous window **152** is provided only as an example and any size shape or configuration may be implemented. In this example, the porous window **152** is positioned approximately symmetrically with respect to the balloon-shaped flow control member **150**. FIG. **7** shows the aortic catheter of FIG. **6** deployed within a patient's aorta illustrating the relative position of the porous window **152** relative to the ostia of the arch vessels. In this example, the porous window **152** is positioned asymmetrically with respect to the balloon-shaped flow control member **150** to accommodate a variation in the geometry of a patient's aortic arch.

In an alternate embodiment shown in FIG. **8**, the flow control member **160** includes a porous middle portion **162** with an inflated or deployed diameter less than the diameter of the aortic lumen when the proximal **124** and distal **120** ends are expanded and occluding the aorta. In the embodiments wherein the middle porous section contacts the aortic lumen the effective perfusion area may be limited to the area at the openings of the ostia since the rest of the porous portion will be effectively occluded by the aortic wall. The advantage of the configuration associated with FIG. **8** is that the middle porous section **162** avoids substantial contact with the aortic wall allowing a greater effective filter and perfusion surface area to the arch vessels since perfusion is free to pass through all the mesh material and into the arch vessels. This enables a finer mesh to be used since the effective filter and perfusion surface area is not limited to the openings of the arch vessels.

The occlusion member **160** of FIG. **8** may be made of different materials which will enable the proximal and distal ends to be more easily inflatable or expandable than the middle porous portion **162** which has the resultant effect of differing outer diameter proportions. For example, the proximal **124** and distal **120** ends may be made of a flexible elastomer such as silicone or latex and the middle portion may be made of a less flexible polyurethane or nylon. Alternatively, another way to achieve the larger ends and a narrower middle portion is to use mechanical supports, external clamps, external heat shrink or the like on the middle portion to essentially restrict the middle portion relative to the ends. In addition, a single material can be used and the desired shape can be achieved by varying the wall thickness of the occlusion member **160**. For example, dipping, molding or extruding the occlusion member are all methods, which may be utilized for creating an occlusion member having a varying wall thickness. Furthermore, the ends of the occlusion member **160** may be fatigued through the manufacturing process to create a thinner or more flexible material.

The embodiment seen in FIG. **9** discloses a flow control member **170** comprising a nonporous balloon with a porous window **172**. The relative position, size and shape of the porous window **172** is provided only as an example, and in other embodiments the porous window **172** may be any desirable position, size or shape. The catheter of FIG. **9** is otherwise similar to the catheter of FIG. **8** as previously described, and the same benefit of increased filter surface area may be obtained. In this embodiment, the smaller diameter of the middle portion also reduces the criticality of positioning the window **172** over the ostia of the arch vessels.

In another embodiment, seen in FIG. **10**, a flow control member **180** comprises a first outer flow control element or outer balloon **187** and a second inner flow control element or inner balloon **184** positioned within the first outer balloon **187**. The first outer balloon **182** comprises a porous material or includes one or more porous sections **182**. The second inner balloon **184** is preferably nonporous. When the second inner balloon **184** is fully inflated, the outer surface of the second inner balloon **184** contacts the inner surface of the first outer balloon **187** preventing escape of perfused fluid through the porous sections of the first outer balloon **187**. When the first inner balloon **187** is fully or partially deflated, perfusion is allowed to resume through outer balloon **187**. In this embodiment, separate lumens connecting to the outer balloon port **186** and the inner balloon port **181** are required for inflating and deflating the first outer balloon **182** and the second inner balloon **184** independently of each other.

In embodiments seen in FIGS. **11** through **17**, the catheter **100** is shown and will be described having a flow control member comprising a plurality of flow control elements. For example, FIG. **11** discloses a flow control member **190** comprising a set of three adjacent flow control elements. In

this embodiment, the flow control elements include a first balloon **192**, a second balloon **194**, and a third balloon **196**. In alternate embodiments, any desirable or practical valves, may be substituted for balloons **192** and **196**.

The first balloon **192**, located nearest the distal end **106** of the aortic catheter **100**, is preferably comprised of a nonporous material, and is intended to occlude the ascending aorta between the coronary arteries and the arch vessels, and to prevent fluid perfused through the second porous balloon **194** from entering the ascending aorta in a retrograde direction. The second porous balloon **194** is positioned adjacent the proximal side of the first balloon **192**. The second balloon **194** is preferably formed of a porous material, includes porous sections, or includes other means for allowing a controlled flow rate of perfused fluid to pass through. The third balloon **196** is located adjacent the second balloon **194** and is preferably comprised of a nonporous material. In variations where the aortic catheter **100** is to be introduced directly into the ascending aorta the balloon position is reversed relative to the aorta such that the first occlusion balloon **192** resides in the descending aorta and the third occlusion balloon **196** resides in the ascending aorta. The purpose of the third balloon **196** is primarily for occluding the aorta to prevent fluid perfused through the porous second balloon **194** from entering the descending aorta. The porous second balloon **194** may be configured with a deployed diameter equal to or greater than the aortic lumen in order to contact the aortic wall after inflation, or it may be configured with a deployed diameter smaller than the aortic lumen so that, after inflation, it is not in substantial contact with the aortic lumen. The advantage of configuring the second porous balloon **194** to contact the aortic wall is that the force or friction generated by contact with the aortic wall may resist migration of the flow control member **190**. The advantage of configuring the porous second balloon to avoid substantial contact with the aortic wall is that a greater effective filter surface area is achieved because perfusion may not be limited to passing through the mesh material over the arch vessels, consequently, a finer mesh may be used while still achieving a desired flow rate at a desired pressure.

Another embodiment of the distal flow control member is seen in FIG. **12**, which discloses a flow control member **200** comprising two flow control elements **202** and **204** spaced apart so that, in use, one flow control element is positioned on each side of the arch vessels. In the embodiment shown, the flow control elements **202** and **204** comprise inflatable balloons. The first flow control element **202**, located nearest the distal end of the aortic catheter **200**, preferably comprises a nonporous section **206** on the distal side of the flow control element **202**, and a porous section **208** located on the proximal side of the flow control element **202**. The second flow control element **204** preferably comprises a nonporous section **210** located on the proximal side of the flow control element **204**, and a porous section **212** located on the distal side of the flow control element **204**. The deployment/perfusion ports **206** are located in the first and second flow control elements **202** and **204**. The same or separate inflation/perfusion lumens may be used for flow control elements **202** and **204**. In an alternate embodiment, only one of the balloons **202** or **204** may include a porous section. Alternatively, the first flow control element **202** and second flow control element **204** may be reversed in orientation such that the non-permeable portions are reversed with respect to the permeable portions. In this position, cardioplegia may be delivered to the aortic root through permeable portion **208** while blood is delivered to the corporeal body through permeable portion **212** and the arch receives blood through arch perfusion ports **112** at a flow sufficient to maintain the viability of the brain.

FIG. **13** discloses a flow control member **220** comprising two flow control elements **222** and **224** spaced apart, as in the previous embodiment, so that, in use, one flow control element is positioned on each side of the arch vessels. However in this embodiment, a mesh or porous filter **226** is coupled between the balloons. In this embodiment, the first and second flow control elements **222** and **224** are nonporous balloons. The balloons may be deployed by using a single deployment/perfusion lumen, or in alternate embodiments, a separate lumen may be used to deploy the flow control elements **222** and **224** independently.

In alternate embodiments, valves of various varieties, such as those described in U.S. Pat. Nos. 5,833,671, 5,827,237 by John A. Macoviak and Michael Ross; and U.S. patent application Ser. No. 08/665,635, filed Jun. 17, 1996, by John A. Macoviak and Michael Ross which have previously been incorporated by reference may be used instead of one or more of the inflatable balloons of the flow control elements previously described. For example, FIG. **14** discloses a primary flow control member **240** similar to that disclosed in FIG. **12**, comprising a first flow control element **242**, a second flow control element or inflatable balloon **244**, and a third flow control element **246**. However, in this embodiment, flow control elements **242** and **246** are valves. Any desirable or practical valves, such as those described in U.S. Pat. Nos. 5,833,671, 5,827,237 by John A. Macoviak and Michael Ross; and U.S. patent application Ser. No. 08/665,635, filed Jun. 17, 1996, by John A. Macoviak and Michael Ross, may be substituted for balloons **192** and **196** which have been described in the previous embodiments. Flow control element **244** is an inflatable balloon comprising a porous material or having porous sections or the like.

The first flow control element **242** is located nearest the distal end **106** of the aortic catheter **100**, and is intended to occlude the ascending aorta between the coronary arteries and the arch vessels when introduced in the retrograde direction by way of femoral access and is sized and configured to prevent fluid perfused through the balloon **244** from entering the ascending aorta in a retrograde direction. The third flow control element **246** is positioned adjacent the distal side of the balloon **244**. The purpose of the third flow control element **246** is primarily for occluding the aorta to prevent fluid perfused through the second porous balloon from entering the descending aorta and to isolate cardioplegia. The balloon **244** may be configured with a deployed diameter equal to or greater than the aortic lumen in order to contact the aortic wall after inflation, or it may be configured with a deployed circumference smaller than the aortic lumen so that, in use, it is not in substantial contact with the aortic lumen. The advantage of configuring the balloon **244** to contact the aortic wall is that the force or friction generated by contact with the aortic wall may resist migration of the flow control member **240** or cannula **100**. The advantage in configuring the balloon **244** to avoid substantial contact with the aortic wall is that a greater effective filter surface area is achieved because perfusion is not limited to passing through the mesh material of the balloon **244** over the arch vessels. Consequently, a finer mesh may be used. Preferably the catheter shaft **102** includes one or more lumens for deployment of the flow control elements **242** and **246** separate from the inflation/perfusion lumen for balloon **244**.

In the embodiment shown in FIG. **15**, the flow control member **250** is shown with valves **252** and **256** being end cap valves that are deployed by inflation or deployment of

the second flow control element **254**. Consequently, the end cap valves **252** and **256** do not require separate deployment lumens, as deployment of the inflatable middle flow control element **254** will deploy them. The end cap valves may be any desired shape or configuration. For example, FIG. **16** shows a flow control member **260** similar to that disclosed in FIG. **15**, but with conical end cap valves **262** and **266**. The end cap valves may be made of any suitable materials such polyurethanes, polyethylene terephthalate (PET), polyvinyl chloride (PVC), polyolefin, latex and ethylene vinyl acetate (EVA).

FIG. **17** shows the embodiment of the catheter of FIG. **15** deployed in an aorta with the first flow control element **252** shown in a semi-collapsed condition. It may be an advantage to wean a patient off cardiopulmonary bypass slowly, after the completion of a procedure, by providing a means for transitioning between complete occlusion of the aorta and perfusion by cardiopulmonary bypass and normal heart function. Reducing the pressure in the second flow control member reduces the support of the flow control members **252** and **256**. Fluid pressure generated by contraction of the ventricle temporarily partially collapses the flow control element **252**. Thus, by adjusting the pressure in the second flow control element **254** downward, a controlled flow of blood from the heart is allowed to enter the arch vessels and/or the descending aorta.

The previous embodiments have been described using a catheter configured for a retrograde approach to the aorta from a peripheral vessel such as the femoral artery. Each of the described embodiments of the invention could easily be modified for alternate deployment means. For example, FIG. **18** shows a catheter **100** configured for central antegrade deployment in the aortic arch through an aortotomy or direct puncture in the ascending aorta. The catheter **100** and flow control member **270** is configured similarly to that disclosed in FIG. **3**, comprising an inflatable balloon with nonporous sections **272** and **276**, and a porous middle portion **274**. In this embodiment, the guidewire lumen **116** may be used for corporeal perfusion after the guidewire is removed or alternatively a separate catheter may be inserted either into the femoral artery or the subclavian to perfuse the corporeal circulation, or alternatively corporeal perfusion can be provided through a corporeal lumen **118** and downstream corporeal port **126** distal to the flow control member **270**. Other embodiments of the invention may be configured for peripheral insertion through the subclavian, femoral or auxiliary arteries, as can be seen in U.S. patent application Ser. No. 09/205,753.

Any embodiments of the catheter of the invention described above may further include auxiliary flow control members. The auxiliary flow control members may be used to further compartmentalize the patient's circulatory system, or may be used for other functions such as assisting in securely anchoring the catheter in a chosen position. Accordingly, the auxiliary flow control members may be inflatable balloons, deployable valves, or combinations thereof. An example of an auxiliary flow control member is seen in FIG. **19**. The catheter of FIG. **19** is configured similarly to the catheter disclosed in FIG. **4**, except that the catheter of FIG. **19** comprises an additional or auxiliary flow control member **292** coupled to the catheter shaft **102** proximate, but spaced apart from, the primary flow control member **290**. The auxiliary flow control member **292** is mounted to the distal portion of the catheter shaft **102** proximal to, but spaced apart from, the primary flow control member **290**. The distance between the primary flow control member **290** and the auxiliary flow control member **292** is between approximately 0.5 cm and 10 cm, and is chosen so that when the aortic catheter **100** is deployed with the primary flow control member **290** over the ostia of the arch vessels, the auxiliary flow control member **292** will be positioned in the descending aorta. Use of an auxiliary flow control member **292** to anchor the catheter **100** may allow the use of a lower inflation pressure in the porous balloon as it is no longer depended on for preventing migration of the catheter **100**. This may avoid possible damage to the aorta, which may result from the use of higher pressures to prevent migration.

The auxiliary flow control member **292** is shown in this embodiment in the form of an expandable inflatable balloon bonded to the catheter shaft **202** by heat welding or with an adhesive. The auxiliary flow control member **292** preferably has a length that is longer than the length of the primary flow control member **290**, or alternatively may be shorter so long as the function of anchoring the catheter **100** is accomplished. Suitable materials for the inflatable anchor member **292** include, but are not limited to, elastomers, thermoplastic elastomers, polyvinylchloride, polyurethane, polyethylene, polyamides, polyesters, silicone, latex, and alloys or copolymers and reinforced composites thereof. In addition, the outer surface of the anchor member **292** may include a friction increasing means such as a friction increasing coating or texture to increase friction between the anchor member **292** and the aortic wall when deployed. In the embodiment shown, the corporeal perfusion ports **126** are located on the catheter shaft **102** proximate the anchoring member.

FIG. **19** illustrates the aortic catheter **100** of the present invention deployed in the aorta illustrating the functional features and material attributes of the flow control member **290** in use. The flow control member **290** is positioned within the aortic arch with the porous middle portion **274** covering the ostia of the arch vessels. A selected fluid, such as oxygenated normothermic blood, oxygenated hypothermic blood, blood substitutes such as PERFLUBRON or other perfluorocarbon compounds, radiopaque dyes for angiography, or the like, is introduced through the flow control member inflation and perfusion lumen **108** into the inflatable flow control member **290**. Some selected fluid may seep out through the porous middle portion **274** during inflation, but at a rate less than the rate at which the selected fluid enters the flow control member **290**. In an alternate embodiment, it may be preferable to initially inflate the flow control member **290** with a more viscous solution, for example a radiopaque contrast agent mixed with saline, that will flow through the porous middle portion **274** at a rate slower than the selected perfusion fluid will leak.

When the correct pressure is attained, the flow control member **290** occludes blood flow through the aortic lumen. The selected fluid used to inflate the flow control member **290** may escape through the porous portion **274** at a known rate into the arch vessels. The flow rate may be adjustable by adjusting the pressure within the flow control member **290**. Contact with the aortic wall and the middle porous portion **274** of the flow control member **290** will reduce or prevent seepage of the selected fluid through sections of the porous middle portion **274** of the flow control member **290** not aligned with the arch vessels. The middle porous portion **274** of the flow control member **290** contacting the aortic wall may also provided resistance to the migration of the flow control member **290** or cannula **100**.

Preferably, the aortic catheter **100** includes one or more location markers **128**, such as radiopaque markers and/or sonoreflective markers, to enhance imaging of the aortic catheter **100** during deployment using standard fluoroscopy,

ultrasound, MRI, MRA, transesophageal echocardiography, or other techniques. A radiopaque location marker **128** may be formed as a ring or disk of dense radiopaque metal such as gold, platinum, tantalum, tungsten, or compounds or alloys thereof, or a ring of a polymer or adhesive material heavily loaded with a radiopaque filler material.

In use, the catheter **100** is advanced up the descending aorta and across the aortic arch, under fluoroscopic or ultrasound guidance with the aid of a guidewire within the guidewire lumen **116**. The aortic catheter **100** is advanced until the primary flow control member **290** is positioned in the aortic arch. This may be determined by reference to the radiopaque marker or markers **128**. Using a multihead cardiopulmonary bypass pump or the like, perfusion of oxygenated blood is started through perfusion lumen **108** and out the perfusion ports **112**. The flow control member **290** is then inflated to occlude the aortic arch using a selected perfusion fluid such as oxygenated blood. When the correct pressure is achieved, the perfusion fluid flows from the flow control member **290** and enters the arch vessels. The rate of flow of the perfusion fluid may be controlled by adjusting the pressure within the flow control member **290**. At the completion of the surgical procedure, auxiliary member **292** is deflated and thereafter the flow control member **290** is allowed to deflate, allowing oxygenated blood to flow from the heart to the arch vessels, the descending aorta, and to the coronary arteries. The heart should then spontaneously resume normal sinus rhythm, however, if necessary, cardioversion or defibrillation shocks may be applied to restart the heart. The patient is then weaned off the bypass and the aortic catheter, and other cannulas, are withdrawn. The alternate embodiment configured for antegrade deployment would be used similarly, except that access to the patient's circulatory system would be made through a central access by an aortotomy or incision directly into the ascending aorta.

In use, the aortic catheter **100** of any of the embodiments described above is introduced into the patient's circulatory system through a peripheral artery such as the femoral artery, by the percutaneous Seldinger technique, through an introducer sheath, via an arterial cutdown or centrally by means of a median sternotomy or mini-thorocotmy.

Modification of the operational characteristics or procedures set forth above for use in vessels other than the aorta for perfusion of blood to branch vessels are readily ascertainable by those skilled in the art in view of the present disclosure.

What is claimed is:

1. A catheter for perfusing a branch lumen connected to a first body lumen in a patient comprising:

an elongated catheter shaft configured for introduction into the first body lumen of the patient, said catheter shaft having a proximal end and a distal end; and

a flow control member coupled to said elongated catheter shaft having an expanded diameter sufficient to block blood flow through the first body lumen when deployed, said flow control member comprising a distal impermeable portion, a middle portion, and a proximal impermeable portion, said middle portion comprising a porous section, whereby a fluid used to inflate said middle portion perfuses through said porous section, perfuse the branch lumen;

wherein said porous section is configured as a window of porous material positioned on one side of said middle portion; and

further comprising at least one auxiliary flow control member coupled to said elongated catheter shaft distal to said flow control member.

2. A catheter for perfusing a branch lumen connected to a first body lumen in a patient comprising:

an elongated catheter shaft configured for introduction into the first body lumen of the patient, said catheter shaft having a proximal end and a distal end; and

a flow control member coupled to said elongated catheter shaft having an expanded diameter sufficient to block blood flow through the first body lumen when deployed, said flow control member comprising a distal impermeable portion, a middle portion, and a proximal impermeable portion, said middle portion comprising a porous section, whereby a fluid used to inflate said middle portion perfuses through said porous section, to perfuse the branch lumen;

wherein said porous section is configured as a window of porous material positioned on one side of said middle portion; and

further comprising at least one auxiliary flow control member coupled to said elongated catheter shaft proximal to said flow control member.

3. A catheter for perfusing a branch lumen connected to a first body lumen in a patient comprising:

an elongated catheter shaft configured for introduction into the first body lumen of the patient, said catheter shaft having a proximal end and a distal end; and

a flow control member coupled to said elongated catheter shaft having an expanded diameter sufficient to block blood flow through the first body lumen when deployed, said flow control member comprising a distal impermeable portion, a middle portion, and a proximal impermeable portion, said middle portion comprising a porous section, whereby a fluid used to inflate said middle portion perfuses through said porous section, to perfuse the branch lumen;

wherein said porous section is configured as a window of porous material positioned on one side of said middle portion; and

wherein said porous section is configured as a plurality of windows of porous material.

4. A catheter for perfusing a branch lumen connected to an aortic arch lumen in a patient comprising:

a catheter shaft having a distal end configured to be inserted into a first body lumen of the patient and navigated into the patient's aortic arch lumen and a proximal portion extending outside the first body lumen of the patient when said distal end is in an operative position and wherein said proximal portion is in fluid communication with an external perfusion pump and is configured to provide blood flow to the patient's cerebral circulation through at least one perfusion port in an exterior of said catheter shaft and at a flow rate sufficient to maintain viability of the patient's brain;

a flow control member positioned proximate the distal end of the catheter shaft configured for expanding from said catheter shaft to at least partially occlude the aortic arch lumen, wherein said flow control member has a distal impermeable portion, a middle portion, and a proximal impermeable portion, said middle portion comprising a porous portion, said porous portion having permeable portions of sufficient size to allow fluid to flow therethrough to the patient's arch vessels and said at least one occlusive end is sized and dimensioned such that when placed in the operative position upstream of the patient's brachiocephalic artery said occlusive end is

capable of expanding radially to a diameter at least the size of an inside diameter of the patient's aortic arch lumen; and

a corporeal perfusion lumen having a distal end configured to reside inside the lumen of the patient's aorta when placed in an operative position and a proximal portion extending outside the first body lumen of the patient and configured for being coupled to said external perfusion pump and of sufficient size and internal diameter to communicate fluid from said external perfusion pump to a corporeal perfusion port proximate said external end to sustain metabolic demands of the patient's body.

5. The aortic catheter of claim 4, wherein said porous portion comprises one or more porous windows.

6. The catheter of claim 4, wherein said porous portion has a deployed diameter less than the deployed diameter of said occlusive end.

7. The catheter of claim 4, wherein a known rate of perfusion can be established by adjusting the pressure within the flow control member.

8. The catheter of claim 4, further comprising at least one auxiliary flow control member coupled to said elongated catheter distal to said flow control member.

9. The catheter of claim 4, further comprising at least one auxiliary flow control member coupled to said elongated catheter proximal to said flow control member.

10. The catheter of claim 4, wherein said porous portion comprises a filter.

11. The catheter of claim 4, wherein said porous portion is comprised of a filter material.

12. The catheter of claim 5, wherein said one or more porous windows comprise a filter.

13. A catheter for perfusing a branch lumen connected to an aortic arch lumen in a patient comprising:

a catheter shaft having a distal end, a proximal portion and a flow control member positioned between said proximal portion and said distal end, said flow control member having a distal impermeable portion, a middle portion, and a proximal impermeable portion, said middle portion comprising a porous portion and having an interior chamber in fluid communication with a perfusion lumen extending along the length of said catheter shaft from at least one perfusion port positioned within said interior of said flow control member to an external perfusion pump located outside the patient's aorta wherein said at least one perfusion port is sized and configured to expand said flow control member to a size sufficient to occlude a patient's aorta and to provide adequate flow to the arch vessels through said porous portion to sustain the metabolic demands of the brain; and at least one auxiliary flow control member coupled to said catheter shaft; and

a corporeal perfusion lumen having a distal end and configured to reside inside the internal lumen of the patient's aorta when placed in an operative position and a proximal portion extending outside the body lumen of the patient configured for being coupled to said external perfusion pump and of sufficient size and internal diameter to communicate fluid from said external perfusion pump to at least one corporeal perfusion port to sustain the metabolic demands of the corporeal body.

14. The aortic catheter of claim 13, wherein said porous portion comprises one or more porous windows.

15. The catheter of claim 13, wherein said porous portion has a deployed diameter less than the deployed diameter of said occlusive end.

16. The catheter of claim 13, wherein a known rate of perfusion can be established by adjusting the pressure within the flow control member.

17. The catheter of claim 13, further comprising at least one auxiliary flow control member coupled to said elongated catheter distal to said flow control member.

18. The catheter of claim 13, further comprising at least one auxiliary flow control member coupled to said elongated catheter proximal to said flow control member.

19. The catheter of claim 13, wherein said porous portion comprises a filter.

20. The catheter of claim 13, wherein said porous portion is comprised of a filter material.

21. The catheter of claim 13, wherein said one or more porous window comprises a filter.

22. An aortic catheter comprising:

an elongated catheter shaft configured for introduction into a patient's aorta and having a proximal end and a distal end; and

a flow control assembly coupled to said elongated catheter shaft having at least one expanded diameter sufficient to block blood flow through the aortic arch when deployed;

said flow control assembly comprising at least one porous inflatable member, whereby a fluid used to inflate said at least one porous inflatable member perfuses at a known rate through said at least one porous inflatable member to perfuse the arch vessels;

wherein said flow control assembly comprises two porous inflatable members, including a distal porous inflatable member and a proximal porous inflatable member, wherein said distal porous inflatable member has a nonporous distal side and a porous proximal side, and wherein said proximal porous inflatable member has a nonporous proximal side and a porous distal side.

23. A catheter for perfusing a branch lumen connected to a first body lumen in a patient comprising:

an elongated catheter shaft configured for introduction into the first body lumen of the patient, said catheter shaft having a proximal end and a distal end;

a flow control member coupled to said elongated catheter shaft having an expanded diameter sufficient to block blood flow through the first body lumen when deployed, said flow control member comprising a distal impermeable portion, a middle portion, and a proximal impermeable portion, said middle portion comprising a porous section, whereby a fluid used to inflate said middle portion perfuses through said porous section to perfuse the branch lumen; and

at least one auxiliary flow control member coupled to said elongated catheter shaft.

24. The catheter of claim 23, wherein said at least one auxiliary flow control member comprises an inflatable balloon.

25. The catheter of claim 23, wherein said at least one auxiliary flow control member comprises a flow control valve.

26. The catheter of claim 23, wherein said at least one auxiliary flow control member is coupled to said elongated catheter shaft distal to said flow control member.

27. The catheter of claim 23, wherein said at least one auxiliary flow control member is coupled to said elongated catheter shaft proximal to said flow control member.

28. The catheter of claim 23, wherein said catheter comprises two auxiliary flow control members, including a first auxiliary flow control member coupled to said elon-

gated catheter shaft proximal to said flow control member and a second auxiliary flow control member coupled to said elongated catheter shaft distal to said flow control member.

29. The catheter of claim **28**, wherein said first and second auxiliary flow control members comprise inflatable balloons.

30. The catheter of claim **28**, wherein said first and second auxiliary flow control members comprise flow control valves.

31. A catheter for perfusing a branch lumen connected to a first body lumen in a patient comprising:

an elongated catheter shaft configured for introduction into the first body lumen of the patient, said catheter shaft having a proximal end and a distal end; and

a flow control member coupled to said elongated catheter shaft having an expanded diameter sufficient to block blood flow through the first body lumen when deployed, said flow control member comprising a distal impermeable portion, a middle portion, and a proximal impermeable portion, wherein said middle portion is configured with a window of porous material positioned on one side of said middle portion.

32. The catheter of claim **31**, further comprising an inflatable balloon positioned within said flow control member.

33. The catheter of claim **32**, wherein said inflatable balloon has a fully inflated state in which said inflatable balloon occludes fluid flow through said window of porous material.

34. A catheter for perfusing a branch lumen connected to a first body lumen in a patient comprising:

an elongated catheter shaft configured for introduction into the first body lumen of the patient, said catheter shaft having a proximal end and a distal end;

a distal porous inflatable member coupled to said elongated catheter shaft, wherein said distal porous inflatable member has a nonporous distal side and a porous proximal side; and

a proximal porous inflatable member coupled to said elongated catheter shaft, wherein said proximal porous inflatable member has a nonporous proximal side and a porous distal side.

35. A catheter for perfusing a branch lumen connected to a first body lumen in a patient comprising:

an elongated catheter shaft configured for introduction into the first body lumen of the patient, said catheter shaft having a proximal end and a distal end; and

a flow control member coupled to said elongated catheter shaft having an expanded diameter sufficient to block blood flow through the first body lumen when deployed, said flow control member comprising a distal impermeable portion, a middle portion, and a proximal impermeable portion, said middle portion comprising a porous section, whereby a fluid used to inflate said middle portion perfuses through said porous section to perfuse the branch lumen;

wherein said porous section is configured as a plurality of windows of porous material.

36. An aortic catheter comprising:

an elongated catheter shaft configured for introduction into a patient's aorta and having a proximal end and a distal end; and

a flow control assembly coupled to said elongated catheter shaft having at least one expanded diameter sufficient to block blood flow through the aortic arch when deployed;

said flow control assembly comprising at least one porous inflatable member, whereby a fluid used to inflate said at least one porous inflatable member perfuses at a known rate through said at least one porous inflatable member to perfuse the arch vessels;

wherein said at least one porous inflatable member is configured with a plurality of windows of porous material.

* * * * *

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(12) **United States Patent**
Ostrovsky et al.

(10) **Patent No.: US 6,447,530 B1**
(45) **Date of Patent: *Sep. 10, 2002**

(54) **ATRAUMATIC ANCHORING AND DISENGAGEMENT MECHANISM FOR PERMANENT IMPLANT DEVICE**

(75) Inventors: **Isaac Ostrovsky**, Wellesley, MA (US); **Michael J. Wallace**, Bellaire, TX (US); **Hannah Kim**, Boxborough, MA (US); **Peter Shank**, Boylston, MA (US); **Kristian DiMatteo**, Maynard, MA (US)

(73) Assignee: **Scimed Life Systems, Inc.**, Maple Grove, MN (US)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **08/978,403**

(22) Filed: **Nov. 25, 1997**

Related U.S. Application Data

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(51) **Int. Cl.**[7] **A61M 29/00**
(52) **U.S. Cl.** **606/200**; 606/108
(58) **Field of Search** 606/200, 198, 606/108

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Primary Examiner—Kevin T. Truong
(74) *Attorney, Agent, or Firm*—Crompton, Seager & Tufte, LLC

(57) **ABSTRACT**

A recoverable thrombosis filter that can be implanted and securely positioned within a vein at a desired location, and can be recovered through an endovenous route even after formation of neointima hyperplasia, is disclosed.

8 Claims, 12 Drawing Sheets

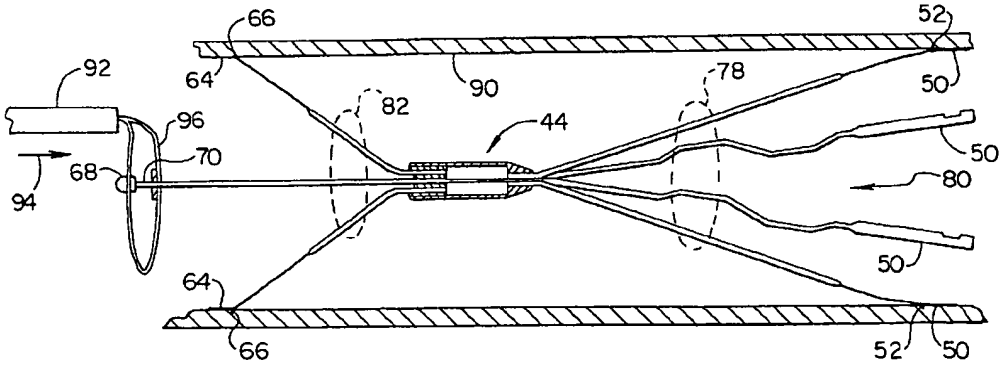
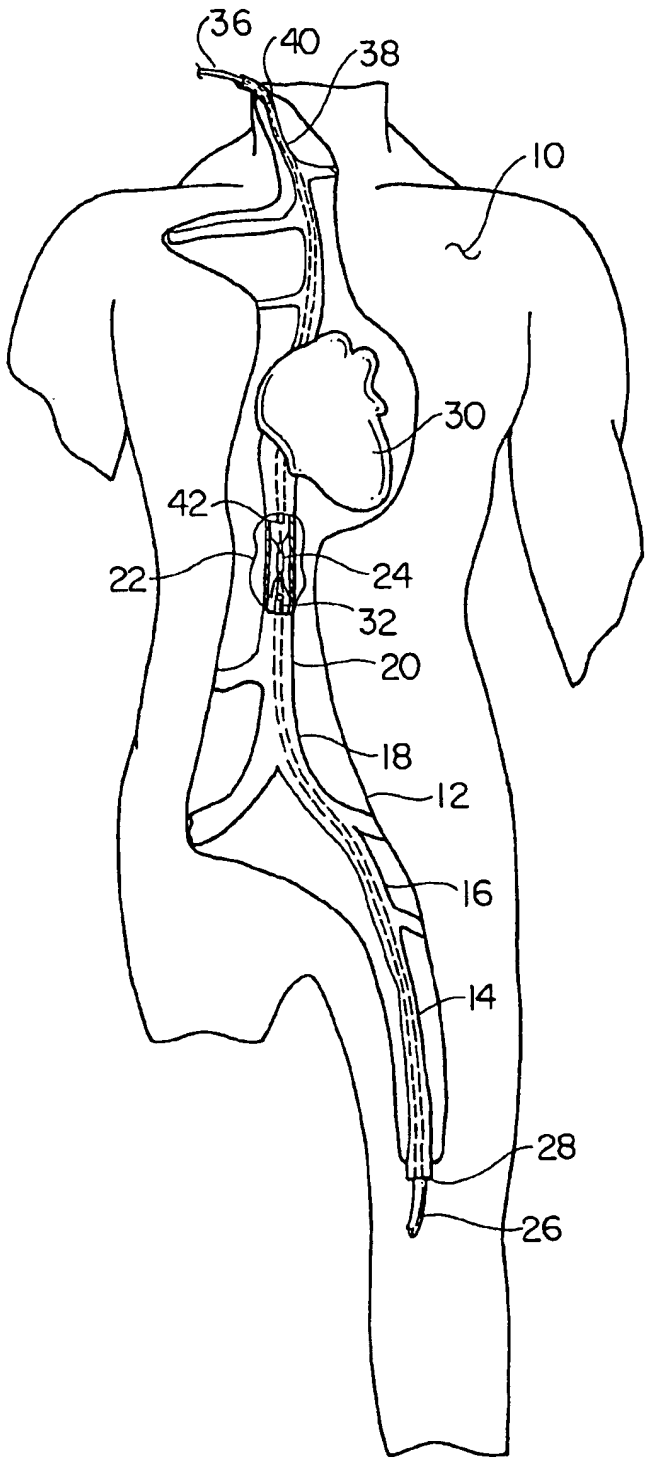


Fig. 1



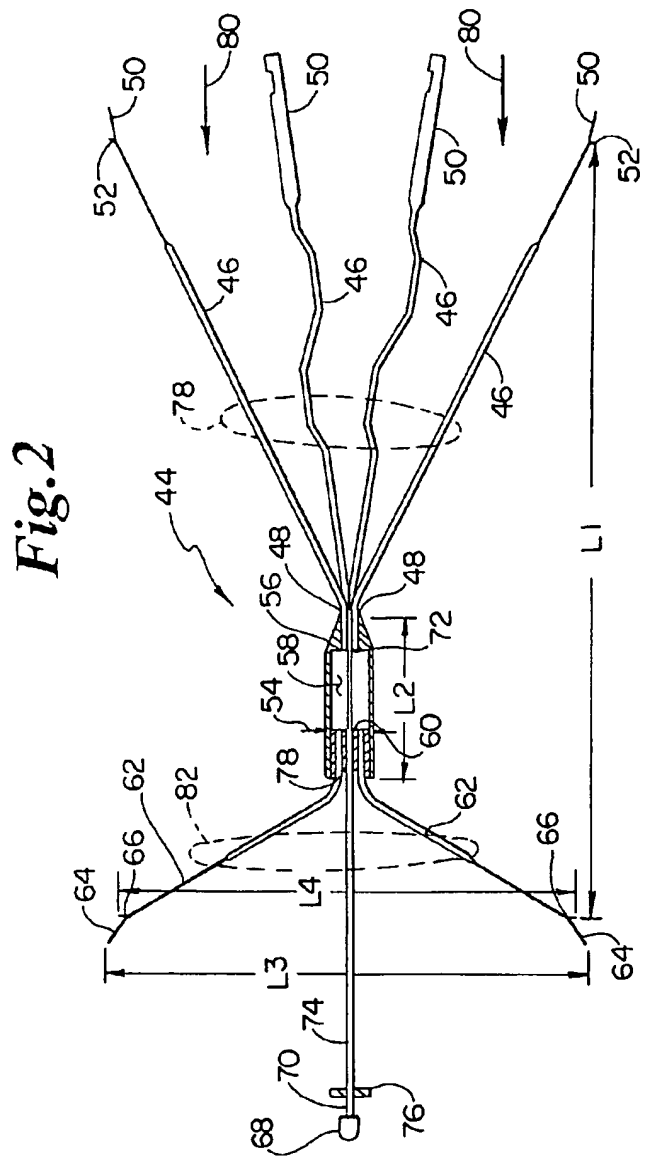


Fig.2
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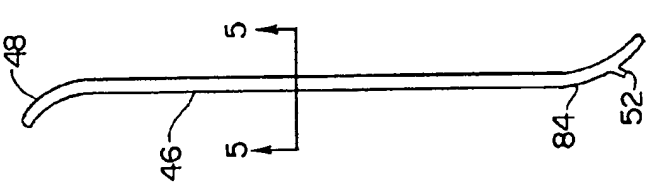
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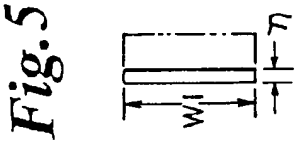
Fig.5
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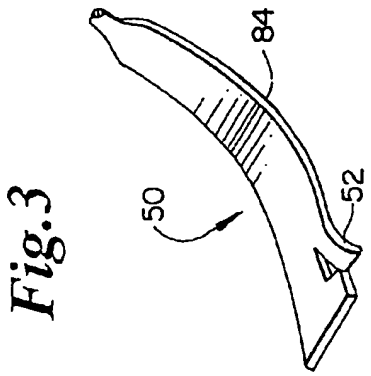
Fig.3
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Fig.6

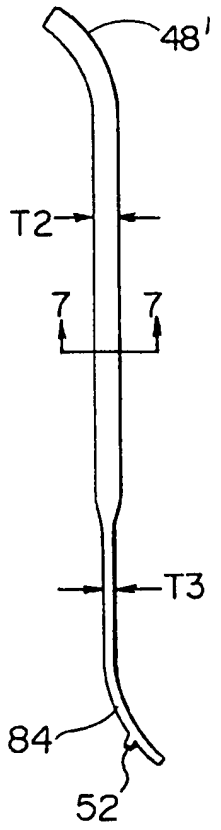

Fig.7

Fig.8

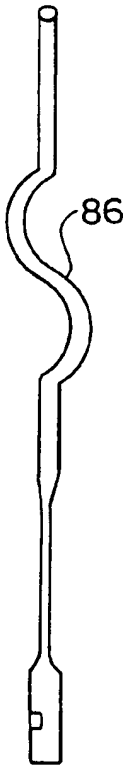

Fig.9

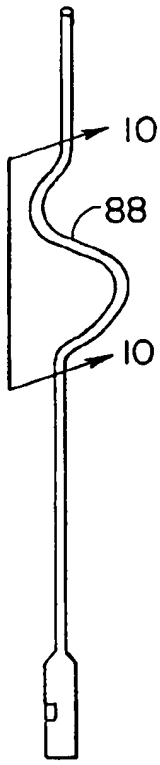

Fig.10

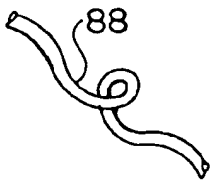

Fig. 11

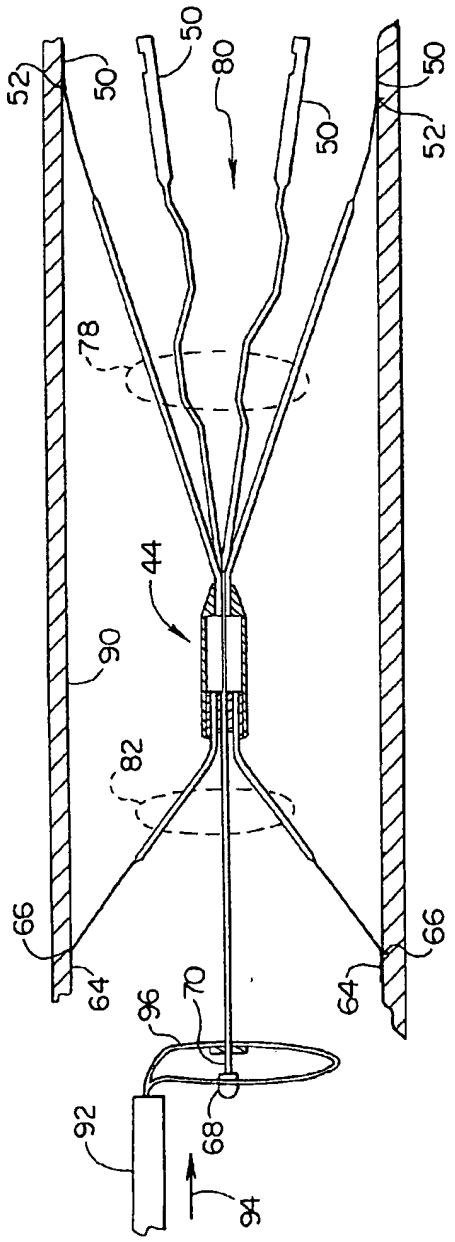
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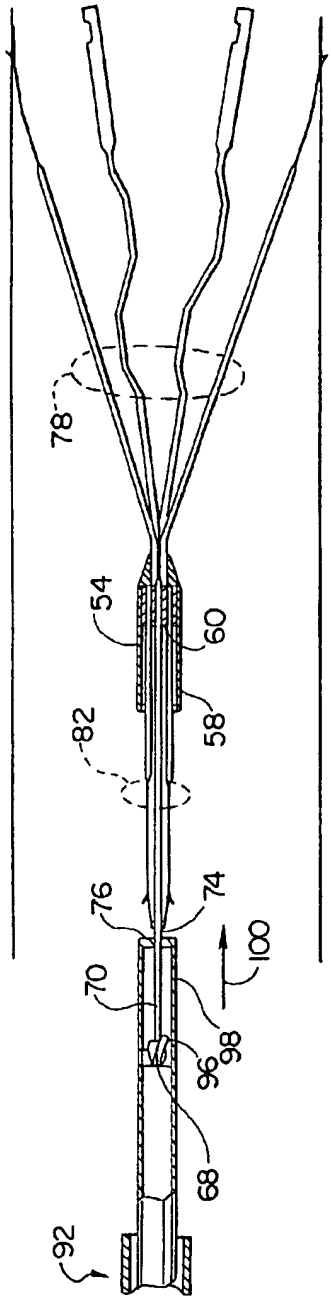
Fig. 12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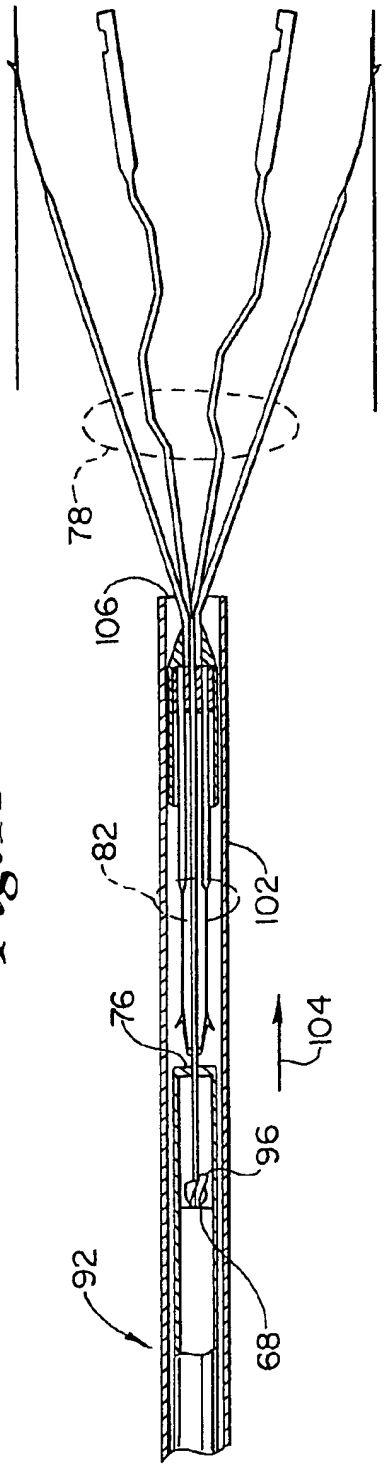


Fig. 13

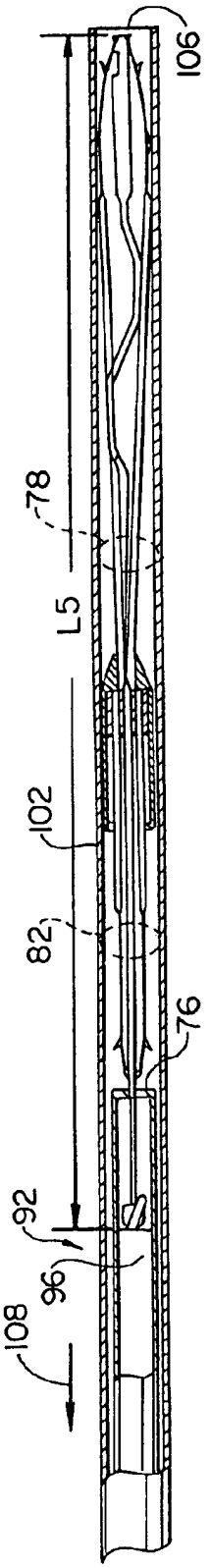


Fig. 14

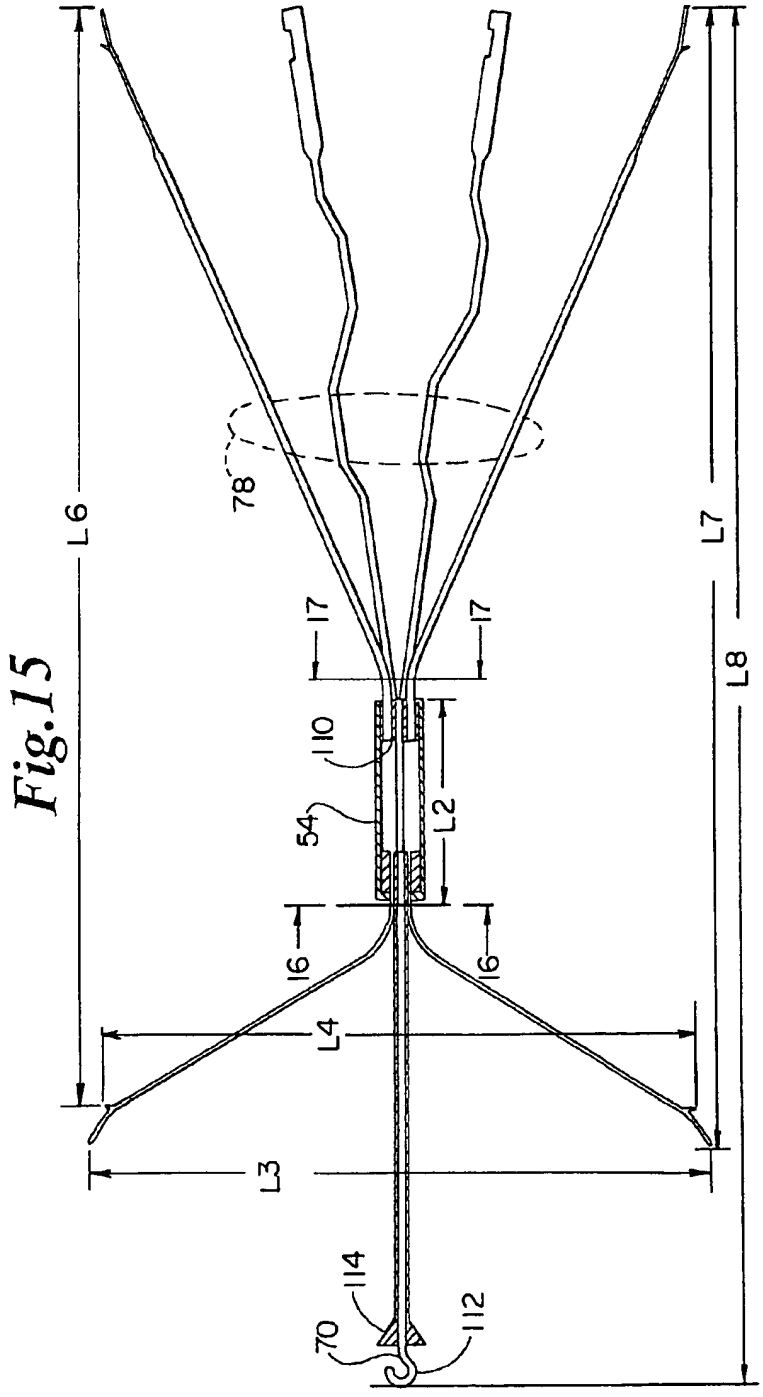


Fig.15

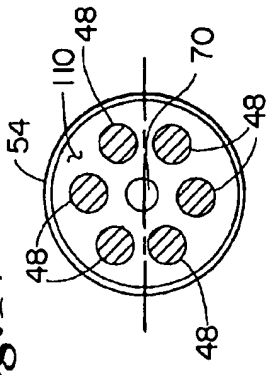


Fig.17

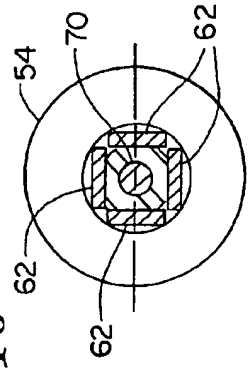


Fig.16

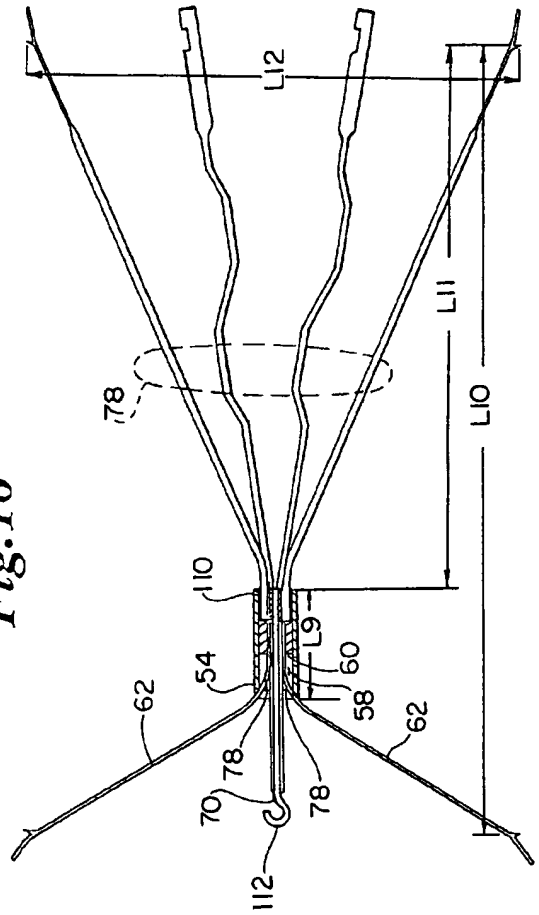

L12
L11
L10
78
110
L9
54
60
58
62
62
78
78
70
112

Fig. 18

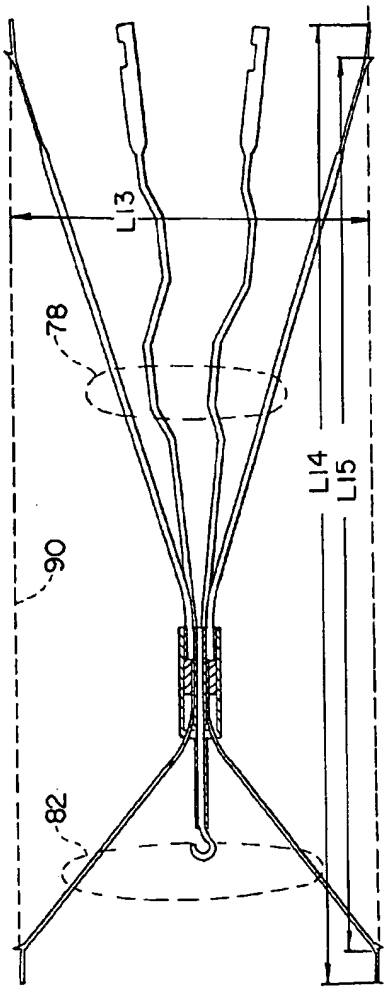

L13
78
L14
L15
90
82

Fig. 19

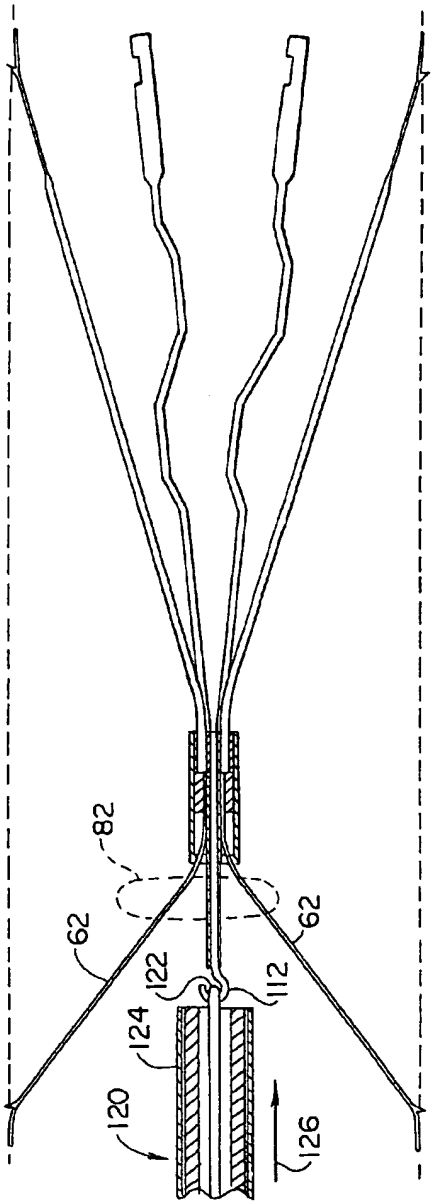


Fig.20

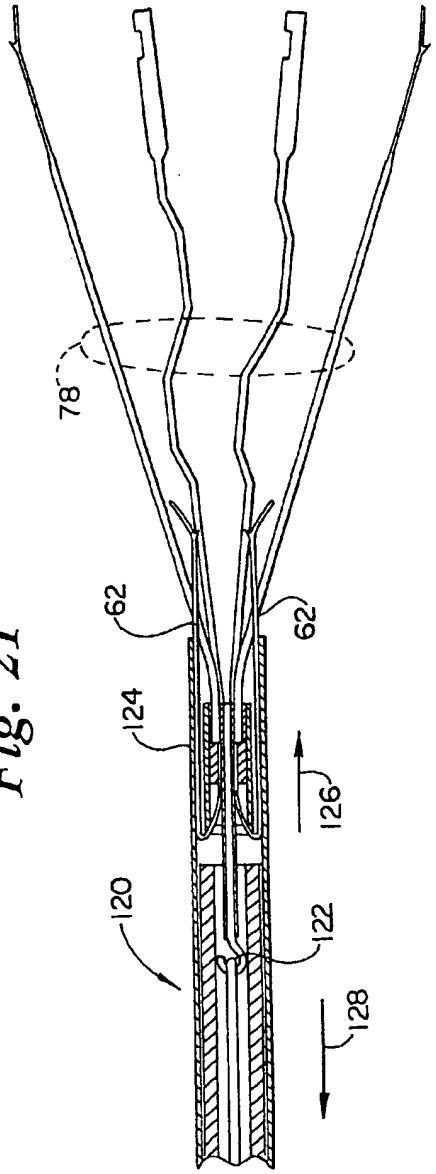


Fig. 21

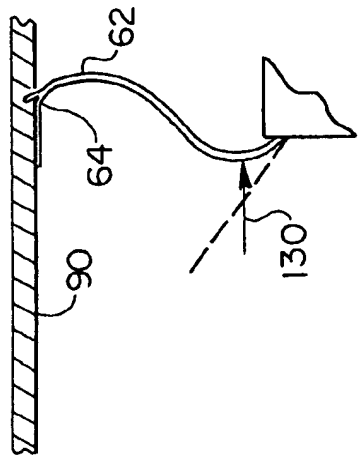


Fig.22C

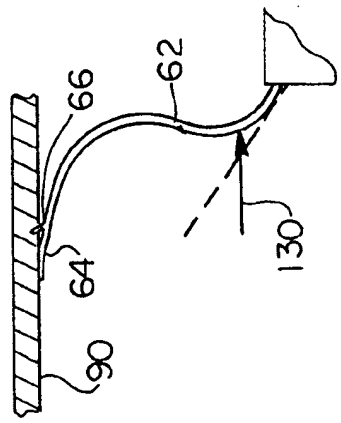


Fig.22B

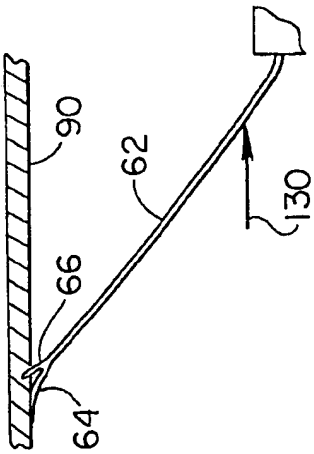


Fig.22A

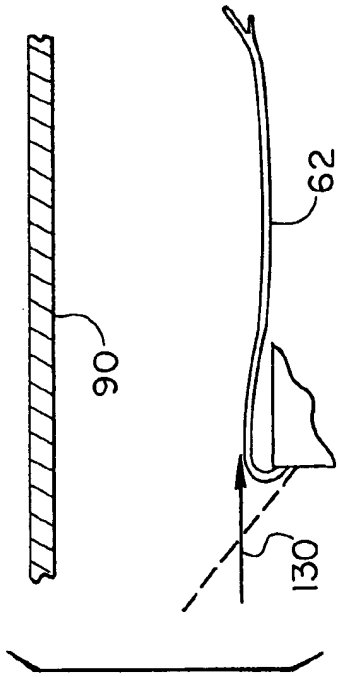


Fig.22E

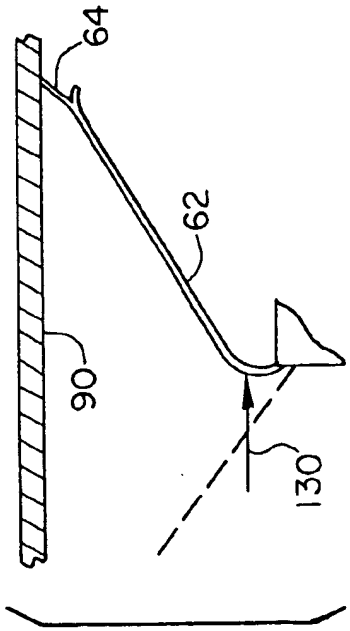


Fig.22D

Fig. 23

Fig. 24

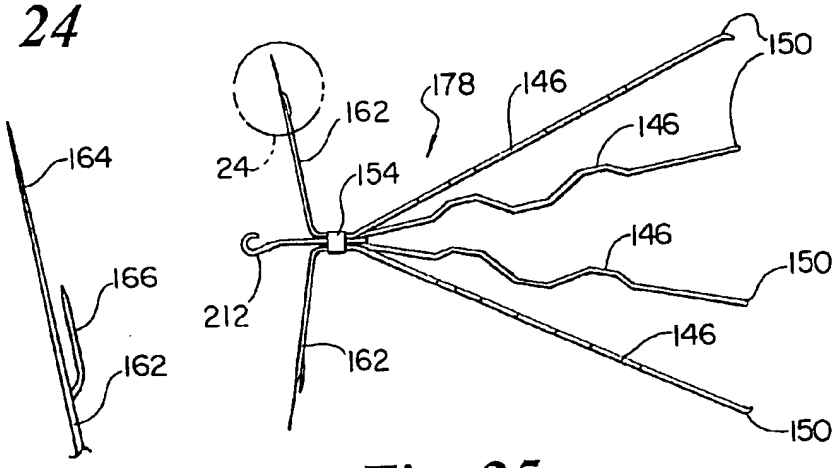


Fig. 25

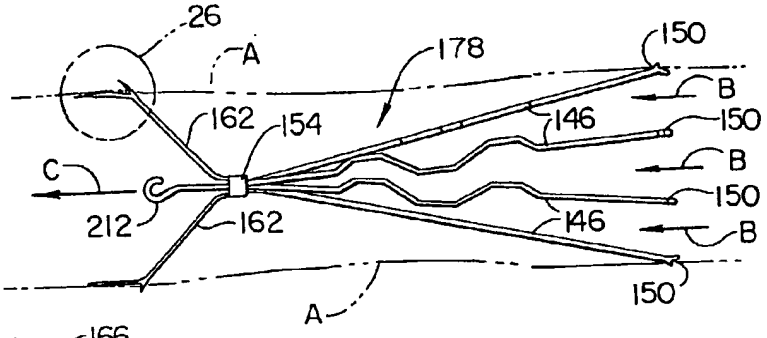


Fig. 26

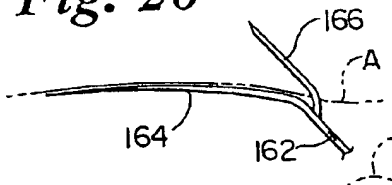


Fig. 27

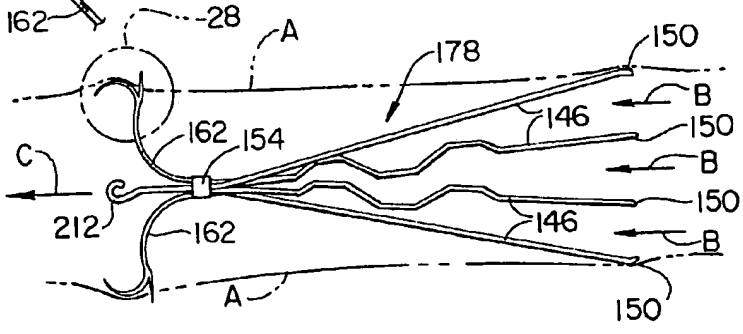


Fig. 28

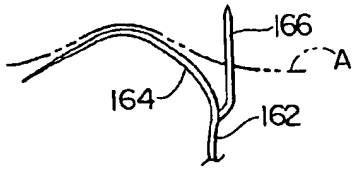


Fig. 29

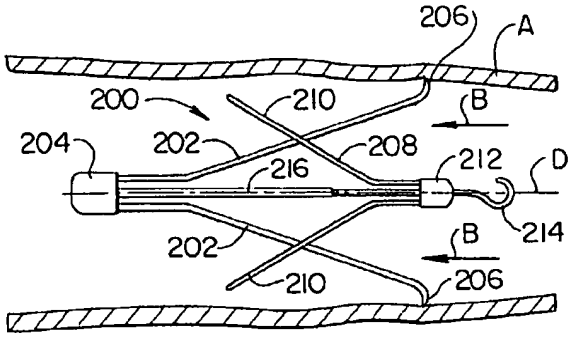


Fig. 30

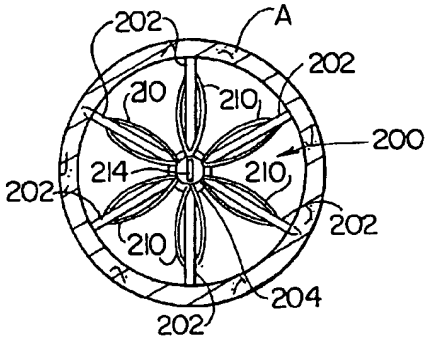


Fig.31

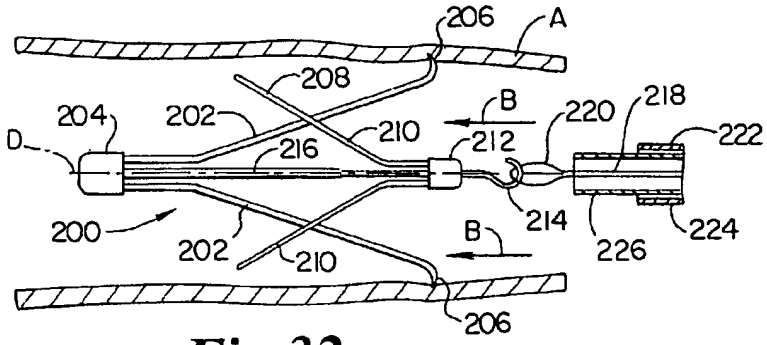


Fig.32

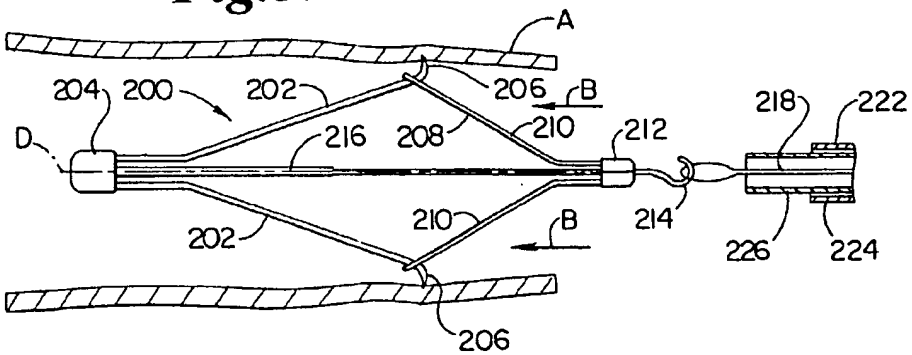


Fig.33

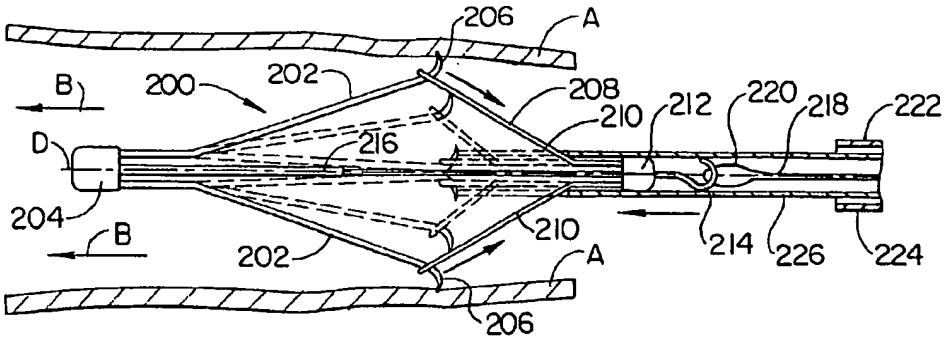


Fig.34

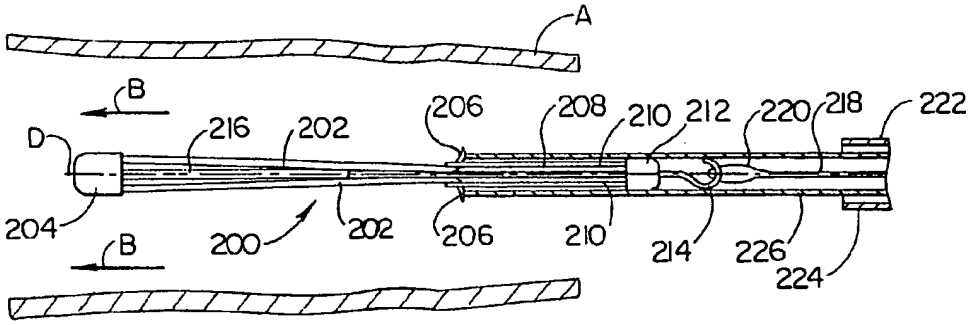
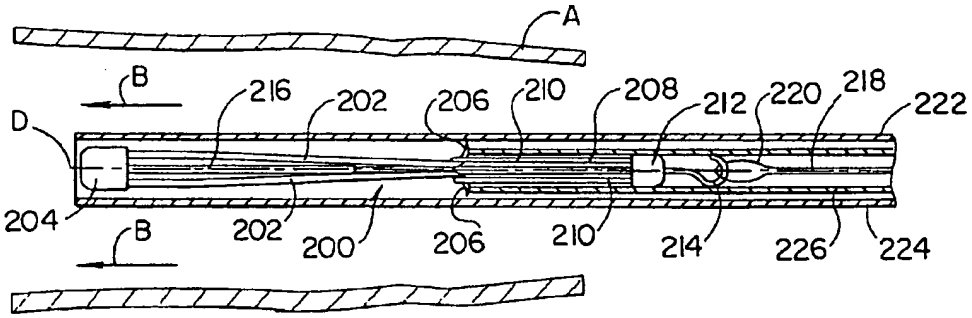


Fig.35



ATRAUMATIC ANCHORING AND DISENGAGEMENT MECHANISM FOR PERMANENT IMPLANT DEVICE

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of application Ser. No. 08/942,531, filed Oct. 2, 1997, which in turn is a continuation-in-part of application Ser. No. 08/757,827, filed Nov. 27, 1996.

TECHNICAL FIELD

The present invention relates to improved thrombosis filters. More particularly, the invention relates to a thrombosis filter that can be percutaneously installed in a selected body lumen at a selected location in the vascular system and is adapted for trapping thrombosis materials or blood clots. Still more particularly, the invention relates to a thrombosis filter that can be percutaneously removed from the vascular system from a single direction.

BACKGROUND OF THE INVENTION

Pulmonary embolism is a recognized medical emergency, and may be caused by venous thrombosis. The venous thrombosis may be caused by blood flow retention, venous intima damage, or coagulation abnormalities. Recognized treatments include administration of anti-coagulant medication therapy, thrombolytic therapy, thrombectomy, and inferior vena cava thrombosis filtering procedures. When an inferior vena cava thrombosis filtering procedure is selected, it can be accomplished using either a laparotomy procedure under general anesthesia, or percutaneously inserting a thrombosis filter under local anesthetic. A laparotomy procedure is a surgical procedure done under general anesthesia, and is susceptible to thrombosis formation due to discontinuance of anti-coagulant therapy prior to such surgery.

A recognized option is to intravenously insert a thrombosis filter in the vascular system, and in particular into the inferior vena cava, which requires only a local anesthetic. Percutaneous filter insertion has been recognized as an effecateous procedure since only a local anesthetic is required; however, such thrombosis filters have been recognized to become affixed to the inner vena cava wall or vein wall by neointimal hyperplasia within a relatively short time after implantation. This process can occur within two or three weeks, and in prior art filter arrangements renders the filter unremovable by a single percutaneous process without incurring significant vessel trauma.

There are a number of thrombosis filters which have been developed with the intent of allowing percutaneous removal. Those prior art thrombosis filters that include substantially linear struts tend to distribute forces along the longitudinal axis of the struts. With the struts deployed outwardly to engage the walls of the lumen, asymmetrical compression of the lumen can cause the struts to be forced together in a manner that causes the struts to do damage to the lumen wall.

As indicated, there are a number of prior art implantable filters. One example is the filter disclosed in U.S. Pat. No. 4,817,600 issued to James Kay Herms, et al., which describes a set of shaped leg portions that are joined at one end and are arranged at an acute angle to the axis of the filter, and form a generally conical arrangement. The shaped legs include hooks at the extremity for hooking into the vein wall and holding the filter in position against the flow of blood within the lumen. Herms, et al. provided for an improved leg structure that would avoid some of the concerns of the filters that used relatively straight struts, and minimized the damage that could occur to the vessel or lumen arising from tipping or tilting of the filter. It did not, however, describe a structure or method for percutaneously removing the filter.

U.S. Pat. No. 4,990,156 to J. Lefebvre describes a filter that may be percutaneously inserted for temporary use in determining whether or not a more permanent filtering treatment is necessary. The device describes a non-aggressive contact of the filter elements with the vessel and describes a number of elements that each have sharpened and roughened portions contacting the vessel wall and holding the filter in position. A sheath is provided to allow removal should the filter not be required for permanent usage. Once deployed, the filter is positioned for definitive use and may not thereafter be readily removed.

U.S. Pat. No. 5,324,304 issued to Erik Rasmussen, describes another form of implantable filter that is self-expandable and can be inserted through use of a catheter which encloses the structure. The anchoring legs are designed to have hooks at the ends for engaging the wall of the vein once deployed. The anchoring elements form part of the filtering structure, and once placed would tend to hook firmly into the vein walls. No structure or method is described for percutaneous removal.

U.S. Pat. No. 5,370,657 to Toshiyuki Irie describes a recoverable thrombosis filter having a structure wherein the holding mechanism and the filtering mechanism is comprised of a number of opposed elements that are held in place by an intermediate tension member. It recognizes that removal may be desirable, and has described a series of shaped end portions that cooperate with the wall of the vessel, without piercing it deeply. For removal, it is necessary that dual percutaneous procedures be worked from opposite ends of the filter. A pair of hooking devices are engaged from the opposite ends, and the two halves of the filter are stretched apart until the connecting tension member breaks. While the two halves of the filter are drawn within a pair of sheaths for withdrawal, this removal procedure requires that two opposed removal structures be administered to the opposite ends of the filter, and that manipulation of the two removal devices be coordinated to grasp the opposed hooking elements such that the filter can be broken in half and withdrawn. This removal process doubles the risk to the patient, and due to the small size of the elements, is relatively difficult to accomplish.

The foregoing described prior art is illustrative of various types of filter structures and handling devices that are known for use in placing and removing thrombosis filters. The prior art structures do not describe filter structures that are readily removable utilizing a single percutaneous removal procedure.

To address the deficiencies in the prior art, the present invention was developed to provide an improved recoverable thrombosis filter that can be removed through a percutaneous procedure even after having been in place for such time as to have had neointimal hyperplasia to have fully developed. Through the use of a unique holding structure and a filtering portion of the thrombosis filter, the filter is structured such that the holding portion can be collapsed from one end through external manipulation and the entire filter drawn within an enclosing structure for removal. These and other more detailed specific objectives of the invention will become apparent to those skilled in the art from

consideration of the drawings and the description of the preferred embodiments.

SUMMARY OF THE INVENTION

The present invention comprises a recoverable thrombosis filter that is recoverable by a single recovery procedure. It includes a plurality of thrombosis filtering elements that are shaped in a predetermined manner and which are joined at one end and are deployed about a longitudinal axis to form a generally conical structure. The filtering elements include shaped ends for engaging an inner lumen wall. A plurality of positioning struts are joined at one end and are deployed in an opposite direction around the longitudinal axis. The positioning struts include wall engaging ends that include projections for engaging the inner wall of the lumen to prevent motion of the filter structure in the direction of deployment of the positioning struts. The anchoring device of the present application can be used with other devices such as stents, stent grafts, vaso-occlusive particles, vascular closure devices, filters and the like.

A recovery mechanism including retracting structure is percutaneously inserted to the vicinity of the filter. The recovery mechanism includes an extensible gripping device, an actuating device, and an outer shield capable of enclosing the filter. The gripping device is manipulated to engage a portion of the retracting structure so that the filter can be held in position. The activating device of the recovery mechanism operates to collapse the plurality of positioning struts to a position where they can be withdrawn by the gripping device into the outer shield. While the outer shield is held firmly in position, the gripping device is further withdrawn and the plurality of thrombosis filtering structures are withdrawn into the shield.

In one embodiment of the removable structure for the thrombosis filter, a retracting mechanism, in combination with the recovery mechanism, causes the plurality of positioning struts to be withdrawn from contact with the inner lumen wall and to be deflected into a substantially parallel relationship with the struts arranged longitudinally in the direction of their original deployment.

In another embodiment, the recovery mechanism engages the removable thrombosis filter and holds it in place while the plurality of positioning struts are moved in the direction opposite of their original deployment and are forced into a generally parallel alignment along the longitudinal axis directed toward the direction of deployment of the filtering elements. Once deflected, the outer shield is held in place and the filter is drawn within the outer shield.

The present invention is thus an improved removable thrombosis filter and method for removal allowing percutaneous removal by a recovery mechanism engaging one end of the filter. Additional features of the invention and the advantages derived therefrom, and the various scopes and aspects of the invention will become apparent from the drawings, the description of the preferred embodiments of the invention, and the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a fragmentary section through a human body from left to right and illustrates a medical procedure of installing the thrombosis filter in the inferior vena cava and removal of the filter by percutaneously entering the venous system at the jugular vein and withdrawing the filter;

FIG. **2** is a side cutaway view of a filter in a relaxed position;

FIG. **3** is a partial perspective view of the vein engaging end of a filter leg member;

FIG. **4** is a side view of a ribbon wire leg member;

FIG. **5** is a cross-sectional view taken at line **5—5** in FIG. **4**;

FIG. **6** is a side view of a round leg member;

FIG. **7** is a cross-sectional view taken at line **7—7** in FIG. **6**;

FIG. **8** is a plan view of a serpentine shaped leg member;

FIG. **9** is a plan view of a spiral shaped leg member;

FIG. **10** is a partial perspective view taken at line **10—10** in FIG. **9**;

FIG. **11** is a side cutaway view of a filter positioned in a lumen about to be engaged for removal;

FIG. **12** is a side cutaway view of a filter positioned in a lumen having a positioning portion collapsed for removal;

FIG. **13** is a side cutaway view of a filter positioned in a lumen having the positioning portion enclosed within a recovery mechanism;

FIG. **14** is a side cutaway view of a filter positioned within a lumen having the entire filter enclosed within a recovery mechanism and ready for removal;

FIG. **15** is a side cutaway view of another embodiment of a filter in a relaxed position;

FIG. **16** is an end view of a joining member taken at line **16—16** in FIG. **15**;

FIG. **17** is an end view of a joining member taken at line **17—17** in FIG. **15**;

FIG. **18** is a side cutaway view of yet another embodiment of a filter in a relaxed position;

FIG. **19** is a side cutaway of the filter of FIG. **18** positioned in a lumen;

FIG. **20** is a side cutaway of the filter of FIG. **18** engaged for removal;

FIG. **21** is a side cutaway of the filter of FIG. **18** with the positioning portion enclosed within a recovery mechanism;

FIGS. **22A–22E** illustrate the deflection and retraction of a flexible anchor member of the type used with the filter of FIG. **18**;

FIG. **23** is side view of yet another embodiment of the recoverable filter in accordance with the present invention;

FIG. **24** is a detailed view of the distal end of an anchoring strut of the filter of FIG. **23**;

FIG. **25** is a side view of the recoverable filter of FIG. **23** disposed in a vessel lumen;

FIG. **26** is a detailed view of the distal end of an anchoring strut as shown in FIG. **25**;

FIG. **27** is a side view of a recoverable filter of FIG. **23** shown in a vessel lumen during the process of removing the filter from the vessel lumen;

FIG. **28** is a detailed view of the distal end of an anchoring strut shown in FIG. **27**;

FIG. **29** is a side view of yet another embodiment of a recoverable filter in accordance with the present invention;

FIG. **30** is an end view of the filter of FIG. **29**;

FIG. **31** is a view of the filter of FIG. **29** and a removal catheter;

FIG. **32** is a view of the filter of FIG. **29** in an early stage of the removal process;

FIG. **33** is a view of the filter of FIG. **29** in a stage of the removal process subsequent to that shown in FIG. **32**;

FIG. **34** is a view of the filter of FIG. **29** in a stage of the removal process subsequent to that shown in FIG. **33**; and

FIG. **35** is a view of the filter of FIG. **29** shown withdrawn into the removal catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** is a fragmentary section through a human body from left to right and illustrates a medical procedure of installing the thrombosis filter in the inferior vena cava and removal of the filter by percutaneously entering the venous system at the jugular vein and withdrawing the filter. This illustrates the body **10** with a cutaway portion **12** that exposes a portion of the vascular system. The femoral vein **14** leads to the external iliac vein **16**. The common iliac vein **18** leads to the inferior vena cava **20**. As illustrated at the cutaway section **22**, a filter **24** is dispersed within the inferior vena cava and is held in place by the structure that will be described. As shown, a catheter tube is inserted at incision **28** into the venous system. As it extends toward heart **30**, it reaches the inferior vena cava **20** and the filter **24** is deployed. The distal end **32** of the catheter structure **26** is shown after deployment of the filter **24**. For withdrawal or removal of filter **24**, a recovery mechanism **(36)** is inserted in the jugular vein **38** at incision **40** and passes through an atrium of heart **30** until its distal end **42** enters the inferior vena cava **20**. The recovery mechanism is not shown in detail in this figure, but will be described in detail below.

FIG. **2** is a side cutaway view of a filter in a relaxed position. The filter **44** has a plurality of shaped filtering elements **46**, each having a mounting end **48** and a wall engaging end **50**. Projections **52** have a length sufficient to engage an associated vein wall (not shown) while being short enough so the vein will not be pierced.

Connecting structure **54** has a frustum shaped end **56** that fixedly attaches the mounting ends **48**. Structure **54** defines a longitudinal cavity **58** within which mounting member **60** is slidably retained.

A plurality of flexible anchoring struts **62** are mounted on mounting member **60** and project outwardly to wall engaging surfaces **64**. Projections **66** function to position and hold the filter **44** in position when engaged to an inner vein wall. A hooking element **68** is affixed to mandrel **70**. An end **72** of mandrel **70** is affixed within the connecting structure **56**. A tubular member **74** has one end affixed to a pushing structure **76** and a second end **78** mounted in the mounting member **60**. Tubing **74** surrounds a mandrel **70** and is coaxially aligned therewith.

In the relaxed state, the length L1 from projection **52** to projection **66** is in the order of 2.0 inches. The length L2 of the joining member **54** is about 0.4 inch. The tip-to-tip length L3 is in the order of 1.25 inches, and the projection-to-projection distance L4 is in the order of 1.2 inches. Various configurations and geometries will be described below, it being understood that when deployed, the filtering portion shown at dashed line **78** will function to restrict the flow of blood clots or thrombosis when blood is flowing in the direction of arrows **80**. At the same time, positioning and holding portion **82** will restrict longitudinal and transverse movement of the filter **44** within the associated lumen or vein. Holding portion **82** preferably centers the device within the lumen.

FIG. **3** is a partial perspective view of the vein engaging end of a filter leg member. The end member **50** has a generally curved structure and is flattened to a desired dimension such that the under surface **84** will slidably engage an associated vein wall. The thickness is selected for the desired flexibility. An outward projection **52** is arranged for engaging the vein wall. A similar configuration is utilized for the anchoring elements.

FIG. **4** is a side view of a ribbon wire leg member. The filter member **46** has the mounting end **48** positioned at a predetermined angle to the longitudinal arrangement of the member **46**. At its other end, the curved portion **84** deflects in the opposite direction and has projection **52**.

FIG. **5** is a cross-sectional view taken at line **5—5** in FIG. **4**. In one configuration, the flat wire has a thickness T1 of about 0.006 inch and a width W1 of about 0.026 inch. It is, of course, understood that differences in thickness relative to width will effect the flexibility of the element.

FIG. **6** is a side view of a round leg member. Again, the leg member has a deflection **48'** and has an upper thickness T2 that can be in the order of 0.016 inch. The lower portion has a reduced cross section with a thickness T3 in the order of about 0.006 inch.

FIG. **7** is a cross-sectional view taken at line **7—7** in FIG. **6**. It illustrates the extent of deflection of portion **48'**.

FIG. **8** is a plan view of a serpentine shaped leg member. As illustrated, serpentine section **86** is provided to yield an improved filtering function when used in combination with other filter members.

FIG. **9** is a plan view of a spiral shaped leg member. In this alternative embodiment, a spiral portion **88** is utilized to enhance the filtering operation.

FIG. **10** is a partial perspective view taken at line **10—10** in FIG. **9**. It illustrates the spiral portion **88**. The design of serpentine portion **86** or spiral portion **88** will be selected in accordance with the number of the filter elements used, the overall size of the filter **44**, the attributes of the lumen in which it will be installed, and the flow of blood being filtered.

FIG. **11** is a side cutaway view of a filter positioned in a lumen about to be engaged for removal. It will be noted that the positioning portion **82** and the filtering portion **78** have their respective members deflected within the confines of vein **90**. As deflected, the curved engaging portions **50** are brought in contact with the inner wall **90**, as are contact portions **64** of the positioning portion **82**. This arrangement provides for the vein walls **90** to provide adequate tension on the positioning portion **82** and the filtering portion **78** to cause the projections **52** and **66** to engage the inner wall without piercing the inner wall.

A filter recovery mechanism **92** is inserted in the direction of arrow **94** until a grasping mechanism **96** is brought in proximity to hooking element **68**. Snare **96** is a looped cord or wire that can be externally manipulated to engage mandrel **70** behind the hooking element **68**. In one configuration, the hooking element **68** and the grasping mechanism **96** can be constructed of materials that can be tracked fluoroscopically.

FIG. **12** is a side cutaway view of a filter positioned in a lumen having the positioning portion collapsed for removal. When the extensible gripping device **96** engages members **68**, it can be utilized to hold member **68** in a relatively fixed longitudinal position. When thus arranged, actuating device **98** is moved in the direction of arrow **100** to engage element **76** to thereby force tube **74** to move along mandrel **70** and cause the positioning portion **82** to collapse. Mounting element **60** is moved within cavity **58** to effect the collapse, and cause the positioning elements to be substantially parallel aligned along the longitudinal axis.

FIG. 13 is a side cutaway view of a filter positioned in a lumen having the positioning portion enclosed within a recovery mechanism. Once the positioning portion 82 has been collapsed, outer shield 102 is moved in the direction of arrow 104 while the gripping device is held steady. When thus positioned, the outer shield 102 is positioned at end 106 to engage the filtering elements 78.

FIG. 14 is a side cutaway view of a filter positioned within a lumen having the entire filter enclosed within a recovery mechanism and ready for removal. Once the positioning portion 82 is enclosed within outer shield 102, pressure can be applied to the gripping member 96 for moving the gripping member in the direction of arrow 108. When thus moved, the outer shield 102 is held firm and end 106 functions to collapse filtering portion 78 such that it can be withdrawn within the confines of outer shield 102. When fully withdrawn within the recovery mechanism 92, the relatively stiff portion of the recovery mechanism 92 has a length L5 of about 2.77 inches.

FIG. 15 is a side cutaway view of another embodiment of a filter in a relaxed position. Elements having similar functions will have a similar reference numeral designation. In this embodiment, filtering portion 78 is mounted in mounting structure 110 enjoining member 54. This configuration eliminates the frustum element 56 and provides additional strength at this structure. A hook 112 replaces the button element 68. Pushing element 76 of FIG. 2 is replaced by a pushing frustum element 114. This frustum configuration provides an improved blood flow and minimizes turbulence. Further, it gives a larger dimension along mandrel 70 such that there is minimization of the tendency to tilt as it is being moved forward as previously described. In this embodiment, dimensions L2, L3, and L4 are similar to those described with regard to FIG. 2. The projection-to-projection length L6 is in the order of 2.1 inches, while the tip-to-tip length L7 is in the order of about 2.22 inches. Finally, the over-all relaxed length of the filter is designated L8, and is about 2.68 inches.

FIG. 16 is an end view of a joining member taken at line 16—16 in FIG. 15. It illustrates the housing 54 mounting positioning elements 62, which number four in this configuration, surrounding mandrel 70 which passes therethrough. This figure is expanded and is not in scale.

FIG. 17 is an end view of a joining member taken at line 17—17 in FIG. 15. It illustrates the mounting member 110 which is mounted in the connecting housing 54, and shows six mounting ends 48 of the filtering members. Mandrel 70 is affixed in the mounting member 110. Again, this figure is in a different scale to that of FIG. 15.

FIG. 18 is a side cutaway view of yet another embodiment of a filter in a relaxed position. In this embodiment, the mounting element 60 is fixedly mounted within channel 58 substantially adjacent to mounting member 110. The mounting ends 78 of positioning struts 62 are restrained by the outer limits of housing 54. A hook 112 is fixedly mounted to mandrel 70 which in turn is secured in mounting element 110. In this embodiment, housing 54 is shorter than the embodiment illustrated in FIG. 2, and has a length L9 of about 0.265 inch. The overall length L10 from a projection-to-projection is in the order of 1.85 inches, and the length L11 from the end of mounting member 110 to the filtering portion 78 projections is in the order of 1.27 inches. The relaxed spacing of the filtering portion L12 is in the order of 1.2 inches. The releasing and collapsing of the anchoring elements 62 in this embodiment will be described below.

FIG. 19 is a side cutaway of the filter of FIG. 18 positioned in a lumen. As shown, positioning portion 82 engages the inner vein wall 90, as does the filtering portion 78. When thus contained, the diameter of the lumen or vein L13 is in the order of 0.866 inch. When installed, the overall length L14 is in the order of 2.25 inches, while the tip projection-to-projection length L15 is in the order of 2.11 inches.

FIG. 20 is a side cutaway of the filter of FIG. 18 engaged for removal. In this embodiment, a recovery mechanism 120 has a gripping device 122 for engaging hook 112. When thus engaged, the gripping device can be held firmly externally, and the outer shield 124 extended in the direction of arrow 126 to engage the legs 62 of positioning portion 82. Outer shield 24 can include a funnel shaped end to assist in directing the filter into the recovery mechanism 120.

FIG. 21 is a side cutaway of the filter of FIG. 18 with the positioning portion enclosed within a recovery mechanism. As shown, the recovery mechanism 120 has had the outer shield 124 moved farther in the direction of arrow 126 such that positioning struts 62 have been bent back upon themselves and are within outer shield 124. As thus positioned, struts 62 are substantially parallel to each other and aligned along the longitudinal axis of the filter and the recovery mechanism 120. When the positioning portion is thus collapsed and retracted, the outer shield 124 is held stationary and the gripping device 122 is moved in the direction of arrow 128 for drawing the filtering portion 78 into outer shield 124. When the filtering portion 78 is fully withdrawn within outer shield 124, the recovery mechanism 120 can be withdrawn from the body.

FIGS. 22A–22E illustrate the deflection and retraction of a flexible anchor member of the type used with the filter of FIG. 18. In FIG. 22A, a flexible anchor member 62 is in a holding position on the inner wall of vein 90. As force is applied in the direction of arrow 130 to the portion of flexible anchor member 62 by the outer shield 124 (see, FIG. 21), the tip 64 and the protrusion 66 are started in a direction to be released from the inner wall 90. In FIG. 22B, the force has been applied at arrow 130 to start deflection of flexible anchor member 62. At this juncture, the protrusion 66 has been removed from inner wall 90 and the tip 64 has started to slide along the inner wall. Anchor member 62 can have a predetermined region of greater flexibility to control the location of the deflection caused by the force supplied at arrow 130.

In FIG. 22C, the force applied at arrow 130 has deflected flexible anchor member 62 such that the end 64 is merely moving along the inner wall surface 90. In FIG. 22D, there is an illustration that the force applied in the direction of arrow 130 has proceeded to a point where flexible anchor member 62 has started to bend back upon itself, and the tip 64 is out of contact with the inner wall of vein 90. Finally, in FIG. 22E, it is shown that force applied in the direction of arrow 130 by the outer shield 124 as bent flexible anchor member 62 back upon itself, such that the outer shield can pass over it.

FIG. 23 is a side view of yet another embodiment of a retrievable filter in accordance with the present invention. The filter as shown in FIG. 23 is in a relaxed, uncompressed state. The filter of FIG. 23 is substantially similar to that of FIGS. 15–22, except as the description below may vary from that of the embodiment of FIG. 15 described above.

The filter of FIG. 23 includes a plurality of filtering elements 146 having wall engaging ends 150. Wall engaging ends 150 as shown in this embodiment are curved to present a rounded convex face to a vessel wall. Collectively filtering elements 146 form a filter portion or array 178. Disposed

distally of filter array **178** are a plurality of legs or anchoring struts **162**. Anchoring struts **162** have proximal and distal ends. A typical distal end is shown in FIG. **24** in detail. The filter also includes a hook **212** to aid in removal of the filter from a vessel. An enjoining member **154** joins filter array **178**, struts **162** proximate their proximal ends and hook **212** together. Struts **162** preferably are formed in a ribbon shape, wherein the thickness of the ribbon is shown in FIG. **23** and the width is perpendicular to the thickness, i.e., directly into the paper.

FIG. **24** is a detailed view of the distal end of a strut **162**. The distal end includes a sharpened portion **166** and a pad portion **164** extending distally beyond sharpened portion **164**. Sharpened portion **164** is sufficiently sharp to penetrate a vessel wall. Pad portion **164** similarly to strut **162**, preferably has a ribbon shape wherein the thickness is shown in FIG. **24** and the width is perpendicular to the thickness, i.e., directly into the paper. As can be seen in FIG. **24**, the thickness of pad portion **164** decreases distally. The decrease in pad thickness **164** can create an increase in flexibility of pad portion **164** distally. A similar increase in flexibility distally along pad portion **164** can be created by varying the material characteristics of pad **164**. Pad portion **164** is preferably flexible enough not to puncture the vessel wall, i.e., the pad portion **164** is preferably atraumatic. In a preferred embodiment of the present invention, the length of sharp portion **164** is between about 2 to 6 millimeters and the length of pad portion **162** is between about 4 to 20 millimeters. In a preferred embodiment, pad portion **164** is more than twice as long as sharp portion **164**.

FIGS. **25** and **26** show the filter of FIG. **23** disposed in a vessel A during normal use. The direction of blood flow is shown by arrows B. The removal of the filter would be in the direction indicated by arrow C by way of hook **212**. Filter elements **146** are shown moderately compressed in comparison to their relaxed state shown in FIG. **23**. As shown in FIG. **26**, sharp portion **166** is penetrating the wall of the vessel A and pad portion **164** is generally parallel to the wall of vessel A.

FIGS. **27** and **28** show the filter of FIG. **23** in the process of being removed from vessel A in the direction indicated by arrow C. As the filter is withdrawn using the same procedure as that of the filter of FIG. **15**, struts **162** will deform generally as shown in FIGS. **22A–22E**. Strut **162** as shown in FIG. **27** is in the approximate position of strut **62** in FIG. **22B**. As the process continues, strut **162** will assume generally the position shown in FIG. **22E**. The ultimate removal of the filter will be accomplished as described with respect to the filter of FIG. **15** above.

FIG. **28** is a detailed view of the distal end of strut **162** as shown in FIG. **27**. Although the configuration of strut **162** in FIG. **27** is similar to that of strut **62** in FIG. **22B**, it can be appreciated that the length of pad portion **164** relative to sharpened portion **166** is substantially greater than element **64** is to element **66** of FIG. **22B**, respectively. As can be appreciated the increased length and increasing flexibility of pad portion **164** distally provides an effective cantilever for retracting sharp portion **166** from the wall of vessel A.

FIG. **29** is a side view of yet another embodiment of filter **200** in accordance with the present invention disposed within a vessel A. Filter **200** has a longitudinal axis D. Blood or fluid flow in vessel A is shown in the direction indicated by arrows B. Filter **200** includes flexible struts **202** generally extending in the first direction along axis D from a hub **204**, while diverging from axis D. A first end of strut **202** is coupled to hub **204**. Second end **206** of strut **202** is preferably sharpened and barbed to engage with the wall of vessel A.

Filter **200** also includes a strut retraction member **208**. Strut retraction member **208** includes a plurality of retraction loops **210** extending from retraction member hub **212** generally in the second direction along axis D. Each of loops **210** preferably loops around a strut **202**. A tether connector **214** extends from hub **212** in the first direction along axis D. A telescoping connector **216** connects hub **204** and retraction member hub **212**.

Various elements of filter **200** such as struts **202** or loops **210** may be formed from nitinol, stainless steel or other biocompatible materials. One skilled in the art would appreciate that the materials described above with respect to the other filter embodiments could advantageously be applied to construct the embodiment **200** as well.

FIG. **30** is an end view of filter **200** shown within vessel A. In the illustrated embodiment of filter **200** there are six struts **202** and loops **210**.

FIG. **31** is a side view of the filter of FIG. **29** to which a tether **218** having a loop **220** is attached to tether connector **214**. Tether **218** is disposed within a catheter **222** having an outer tubular member **224** and an inner tubular member **226**. Assuming that, for example, filter **220** is disposed in the inferior vena cava, catheter **222** may be advanced to the filter from a femoral vein access point. Outer tube **224** and inner tube **226** are preferably formed from biocompatible materials including polymers known to those skilled in the art. The materials must be of sufficient strength and rigidity or flexibility to accomplish the procedure described below.

FIG. **32** is a side view of the filter of FIG. **29** wherein the retraction member **208** is being pulled in the first direction such that loops **210** are advancing along and engaging struts **202**. FIG. **33** is a side view of filter **200** of FIG. **29** wherein inner tube **226** of catheter **222** has been brought into engagement with loops **210**. In dashed lines, inner tube **226** is shown being advanced in a second direction over loops **210** such that struts **202** are brought from a first position engaging the walls of vessel A to a second position adjacent axis D of filter **200**.

FIG. **34** is a side view of filter **200** shown in FIG. **29**. In FIG. **34** struts **202** are shown disposed in the second position. Second ends **206** of struts **202** have been brought into contact with the distal end of inner tube **226**.

FIG. **35** is a side view of filter **200** of FIG. **29** in which filter **200** has been withdrawn into outer tube **224** of catheter **222**. Filter **200** could now be removed from the patient through outer tube **224**, or filter **200** and catheter **222** could be simultaneously removed from the patient.

It can be appreciated that performing the steps of removal process in reverse would provide a method of placing filter **200** in vessel A as shown in FIG. **29**. In a preferred method, however, hubs **204** and **212** would be spaced as shown in FIG. **29** prior to placement in catheter **222**. After deployment of filter **200**, as shown in FIG. **29**, tether **218** and catheter **222** can be removed from the patient such that filter **200** may remain in place for an extended period of time.

From the foregoing, it is understood that various configurations and selection of materials will provide suitable removable filter structures that may be utilized in conformance with the inventive concepts described herein. In general, it is understood that the materials must be suitable for implantation in a human body and will remain intact without adding contaminants to the blood stream. The selection of materials will also determine the flexibility and resiliency of the various members. The various components of the filter can be constructed of a class of elastic materials including nitinol, stainless steel, platinum, tungsten,

titanium, and chromium alloys. The shaping and bonding structures are those available in the construction of thrombosis filters of the class described.

Having described the various embodiments and methods of the invention in conjunction with the drawings, it can be seen that the various stated purposes and objectives have been achieved, and that various modifications and extensions will be apparent to those skilled in the art while remaining within the spirit and scope of the invention. Accordingly, what is intended to be protected by Letters Patent is set forth in the appended claims.

What is claimed is:

1. An improved recoverable filter comprising:

a. a plurality of thrombosis filtering means when deployed in a first direction for retaining thrombosis material moving in a second direction;

b. a plurality of positioning means coupled to said plurality of thrombosis filtering means, said plurality of positioning means having an associated plurality of wall engaging means deployed in said second direction for engaging an associated inner lumen wall and for restricting movement in said second direction; and

c. retracting means for retracting said plurality of positioning means and said plurality of thrombosis filtering means in response to externally percutaneously applied controls for allowing removal in said second direction; wherein said retracting means includes holding means for holding said plurality of positioning means steady in a longitudinal direction; and collapsing means for forcing said plurality of positioning means toward the first direction.

2. A filter as in claim 1, wherein said retracting means further includes:

enclosing means for enclosing said plurality of positioning means and said plurality of thrombosis filtering means for removal in said second direction.

3. An improved recoverable thrombosis filter comprising:

a. a filtering portion having a plurality of shaped filter elements, each of said plurality of shaped filter elements having a joining end and an inner vein wall engaging end;

b. a positioning portion having a plurality of shaped flexible anchor members, each of said plurality of shaped flexible anchor members having a mounting end and a holding end to engage an inner vein wall to impede motion in a first direction;

c. a joining member intermediate said filtering portion and said positioning portion, said joining member having a first end coupled to said joining end of each of said plurality of shaped filter elements and having a coupling portion;

d. a mounting member retained by said coupling portion, said mounting member coupled to said mounting end of each of said plurality of shaped flexible anchor members; and

e. a fastening device coupled to said mounting member, whereby said plurality of shaped flexible anchor members are collapsed from holding contact with the inner vein wall when pressure is applied to said fastening device to thereby allow encapsulation of the thrombosis filter for removal.

4. A filter as in claim 3, wherein said coupling portion includes a longitudinal cavity having a leading end and a trailing end, and said mounting member is fixedly positioned within said longitudinal cavity adjacent to said first end of said joining member, thereby closing said trailing end of said longitudinal cavity; and a closure member affixed to said leading end of said longitudinal cavity.

5. A filter as in claim 4, wherein said mounting end of each of said plurality of shaped flexible anchor members pass through said closure member, and wherein said fastening device includes a mandrel passing through said closure member, said mandrel having a first end affixed to said mounting member, and having a second end; and a hooking device coupled to said second end of said mandrel.

6. An improved recoverable filter comprising:

a. thrombosis filtering means to be deployed in a first direction for filtering and retaining thrombosis materials moving in a second direction;

b. holding means for holding an associated inner lumen wall and for restricting movement in said second direction; said holding means includes a plurality of positioning means, each having first end means coupled to said plurality of shaped thrombosis filter means and deployed about a longitudinal axis and extending generally in said second direction, and having a second end; and a plurality of engaging means, each of said plurality of engaging means, coupled to said second end of an associated one of said plurality of positioning means, and arranged for engaging an associated inner lumen wall for restricting movement in said second direction;

c. joining means for joining said thrombosis filtering means to said holding means; and

d. retracting means for retracting said holding means and said thrombosis filtering means in response to externally applied pressure for allowing removal in said second direction wherein said retracting means includes collapsing means for collapsing said plurality of positioning means in said first direction.

7. A filter as in claim 6, wherein said thrombosis filtering means are arranged around said longitudinal axis and includes a plurality of shaped thrombosis filter means deployed outwardly about said longitudinal axis and extending generally in a first direction and arranged for retaining thrombosis materials traveling in a second direction.

8. A filter as in claim 6, wherein said retracting means includes:

deflection means for deflecting said plurality of positioning means in said first direction.

* * * * *

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United States Patent [19]

Andersen et al.

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[45] Date of Patent: Nov. 22, 1994

[54] **TUBULAR MEDICAL PROSTHESIS**

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[22] Filed: **Jul. 13, 1992**

Related U.S. Application Data

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[51] **Int. Cl.**[5] **A61F 2/02**; A61F 2/06; A61M 29/02

[52] **U.S. Cl.** **623/11**; 606/194; 623/1

[58] **Field of Search** 623/1, 11, 12, 66; 606/191-200; 600/36

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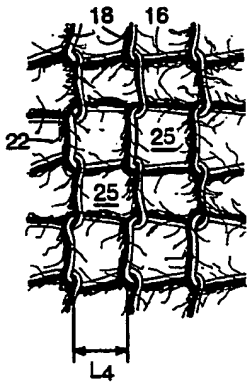
[57] **ABSTRACT**

A tubular prosthesis including a tubular wall portion of loosely interlocked pattern, e.g. of knitted loops, constructed to function within a body lumen. The loops are preferably formed of co-knitted strand materials. A first strand material is a metal strand that structurally defines the tubular shape of the prosthesis and maintains the shape when positioned in the lumen. A second strand material is a predetermined substance selected to provide desired characteristics to the wall of the prosthesis.

29 Claims, 11 Drawing Sheets



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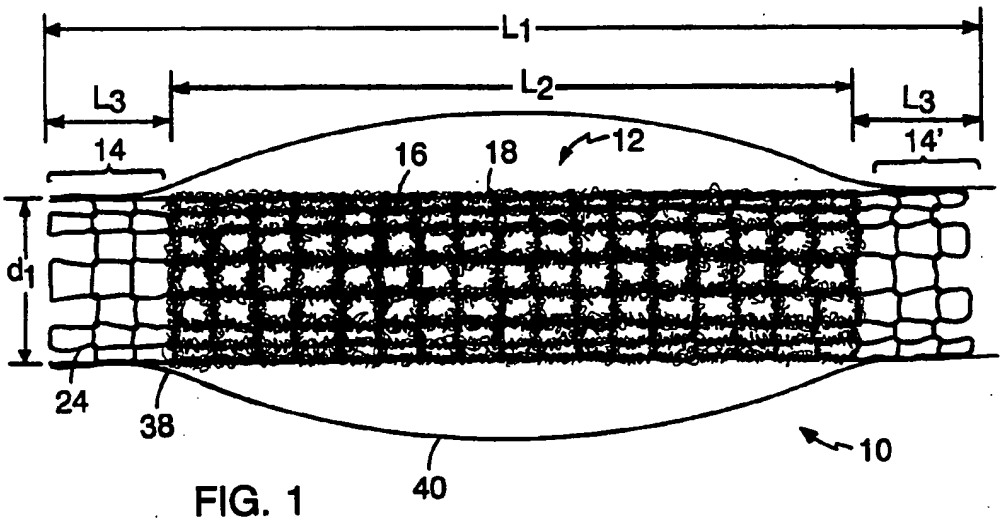


FIG. 1

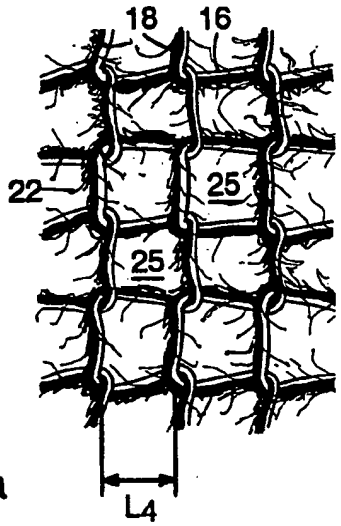


FIG. 1a

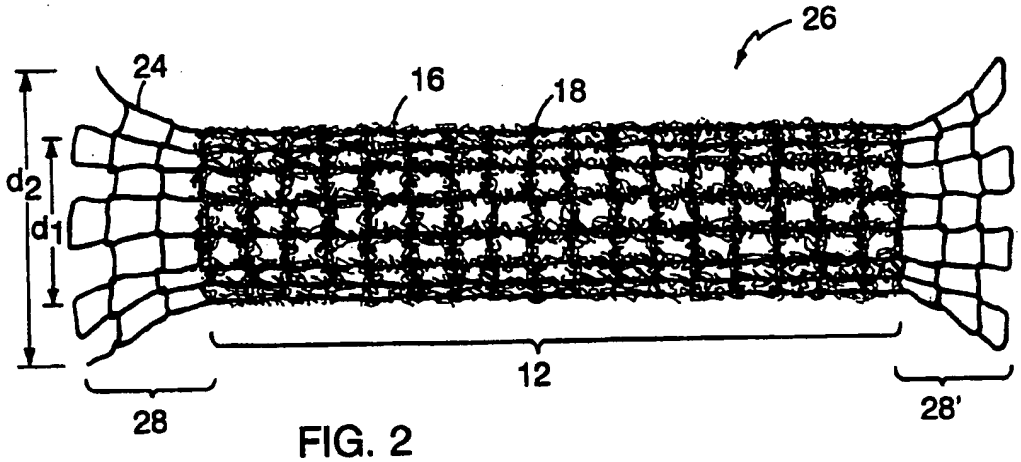


FIG. 2

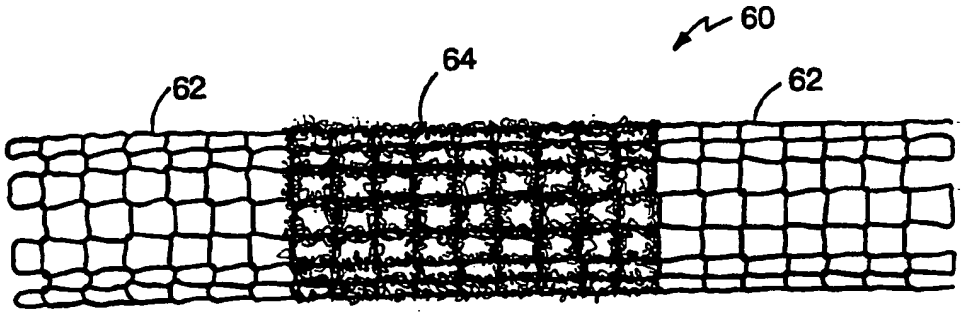


FIG. 4

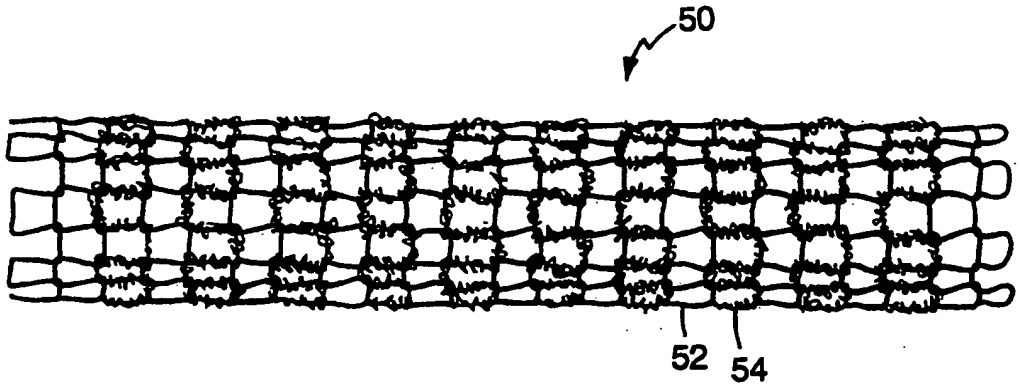


FIG. 3

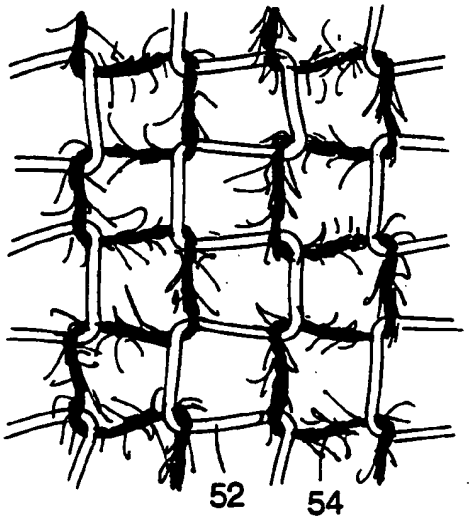


FIG. 3a

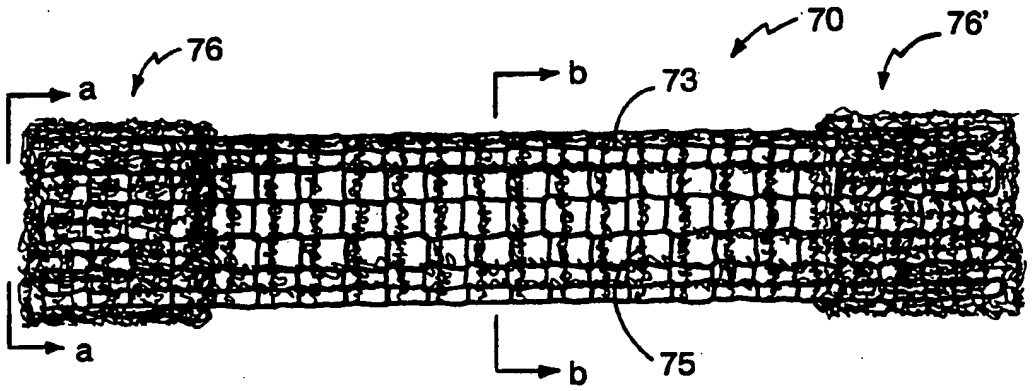


FIG. 5

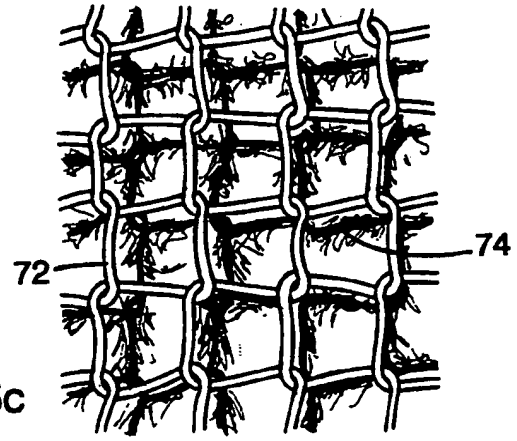


FIG. 5c

FIG. 5a

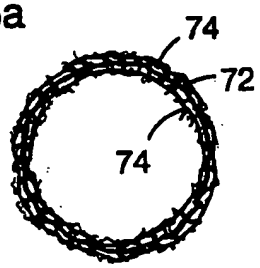
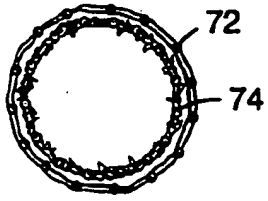


FIG. 5b



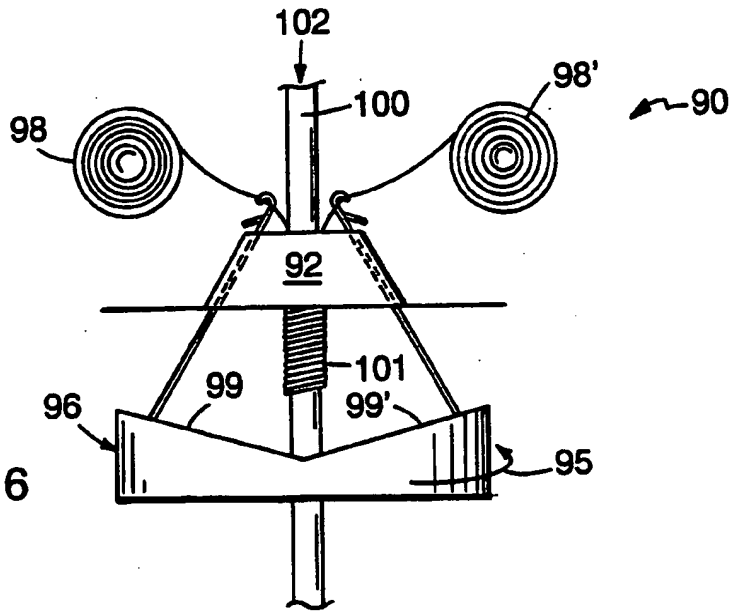


FIG. 6

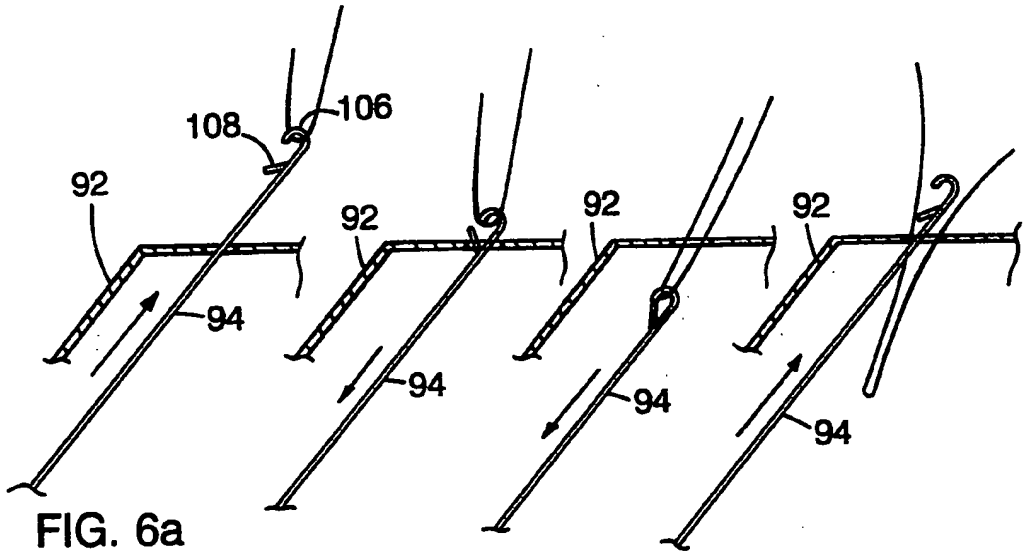


FIG. 6a FIG. 6b FIG. 6c FIG. 6d

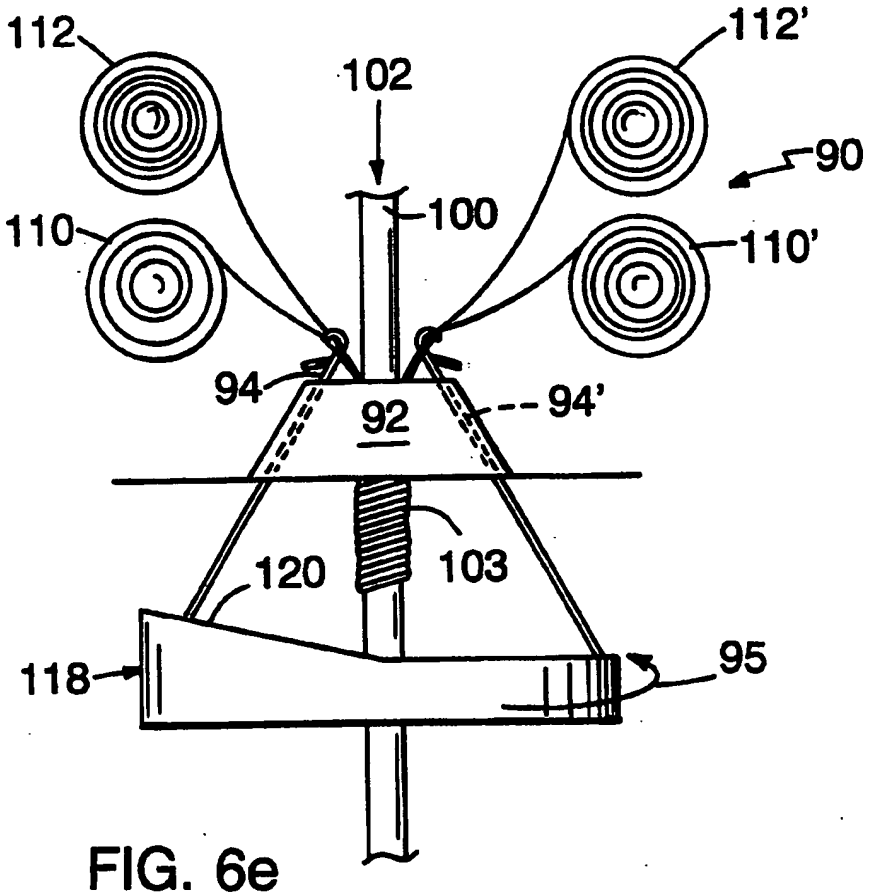


FIG. 6e

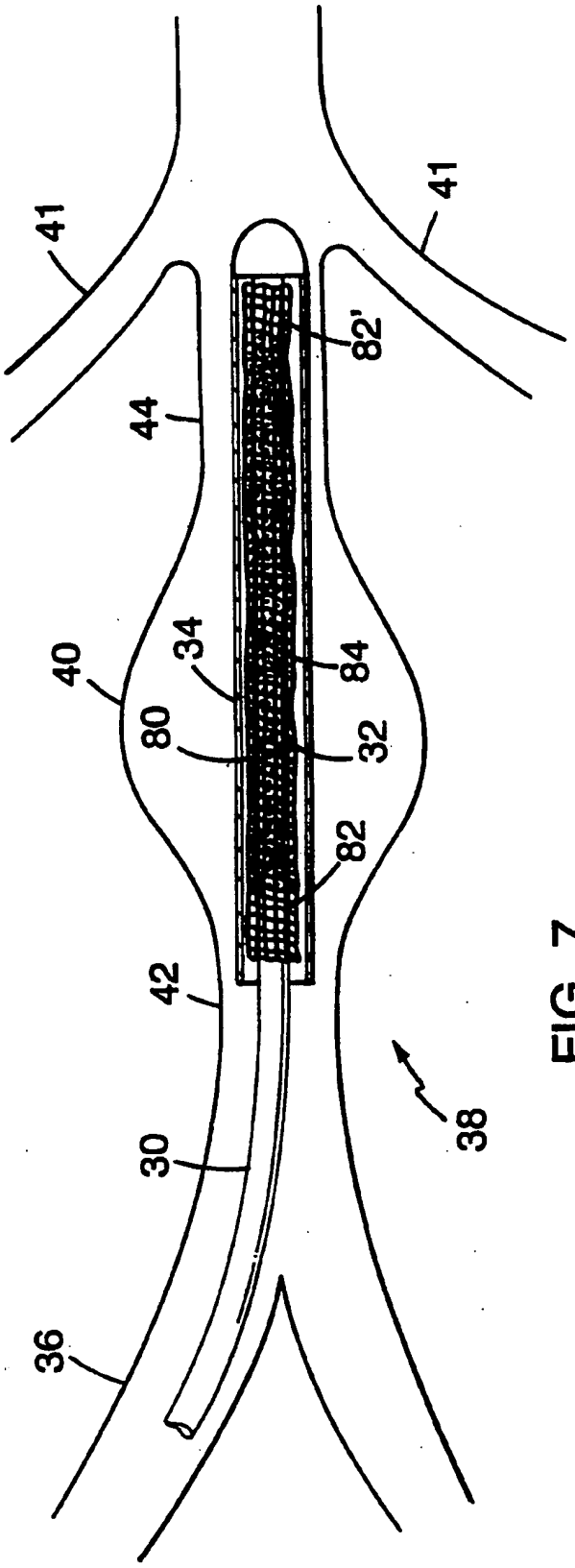


FIG. 7

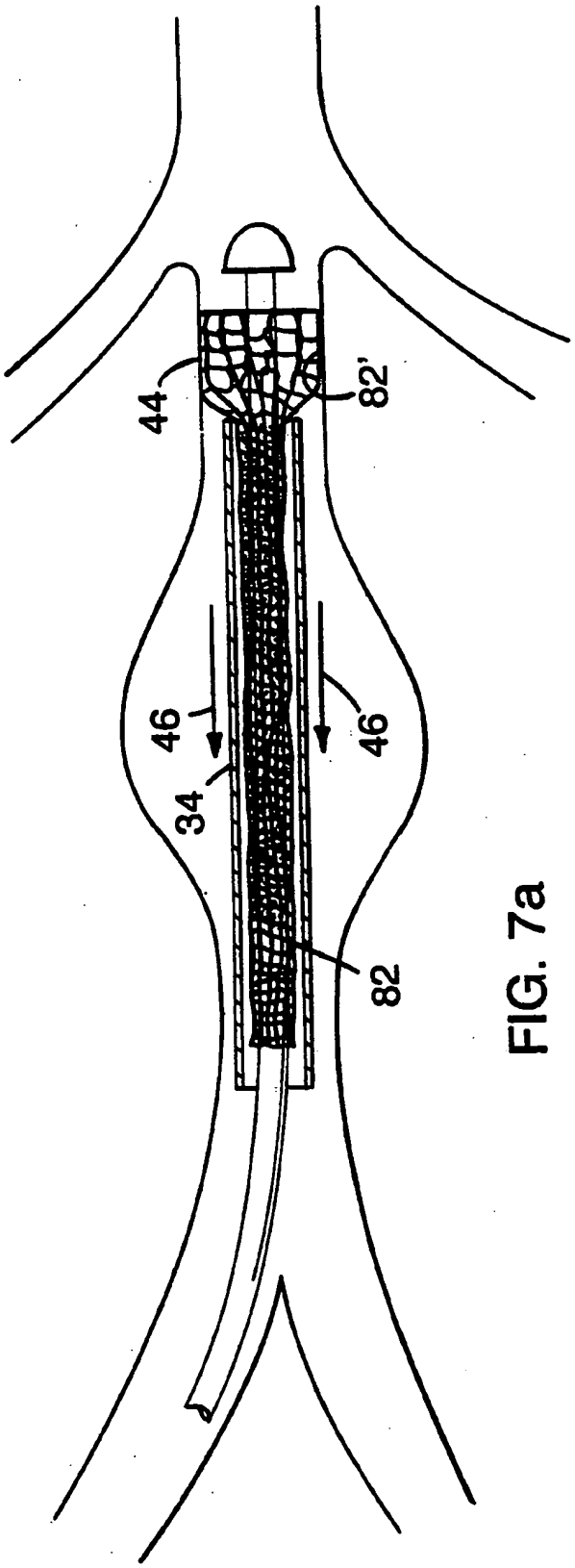


FIG. 7a

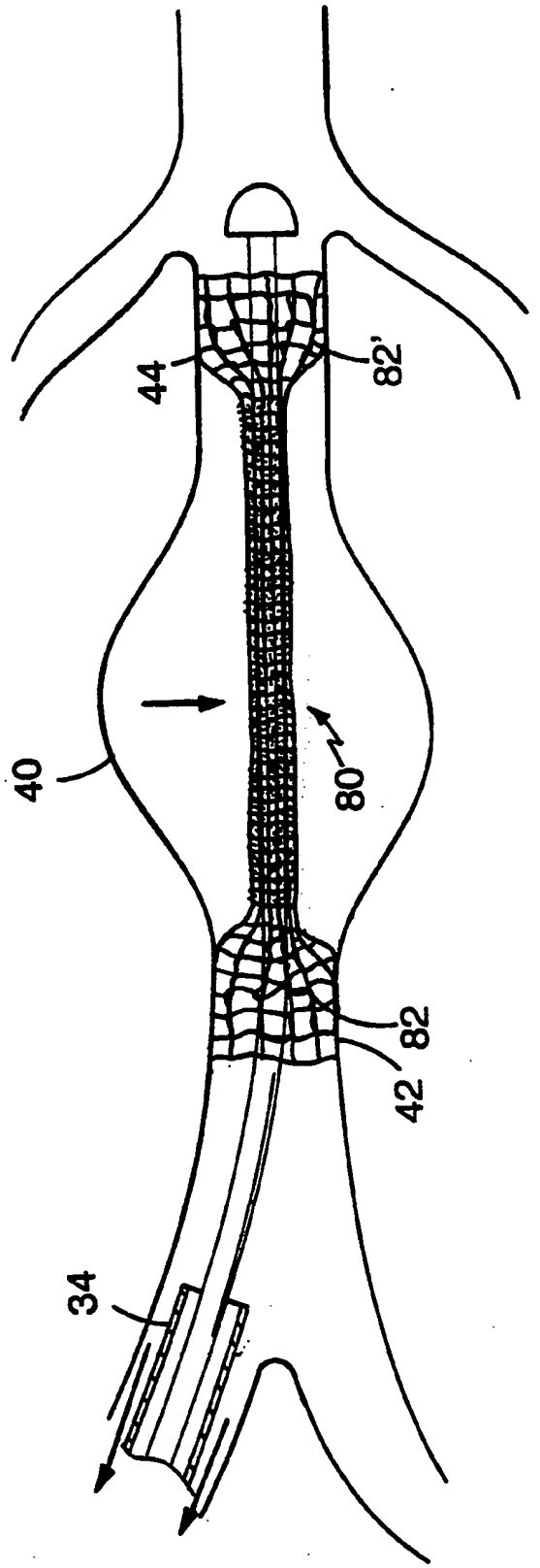


FIG. 7b

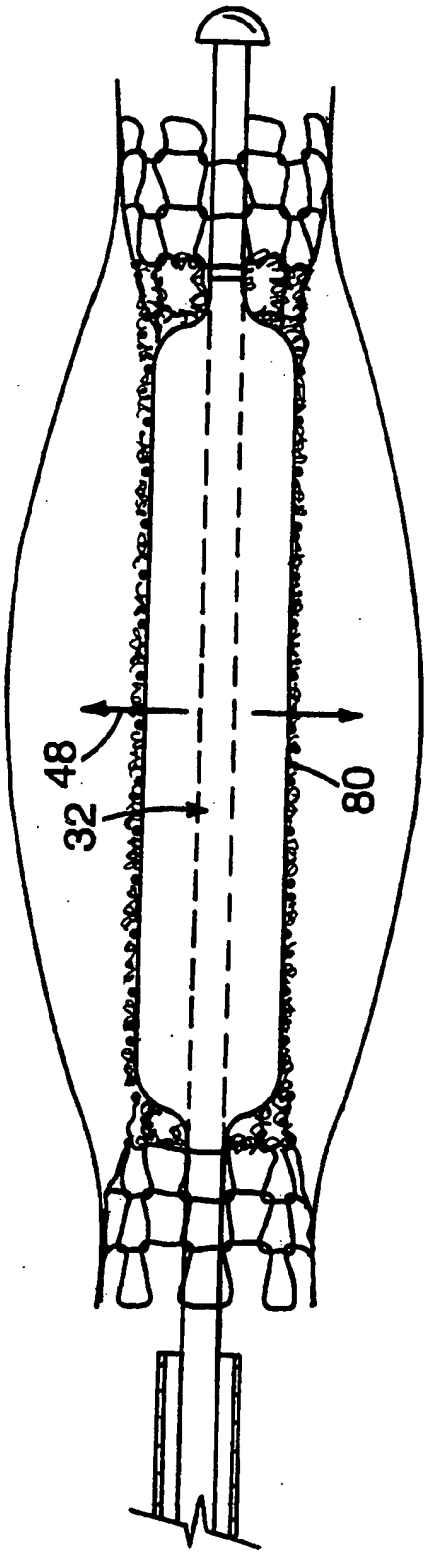


FIG. 7c

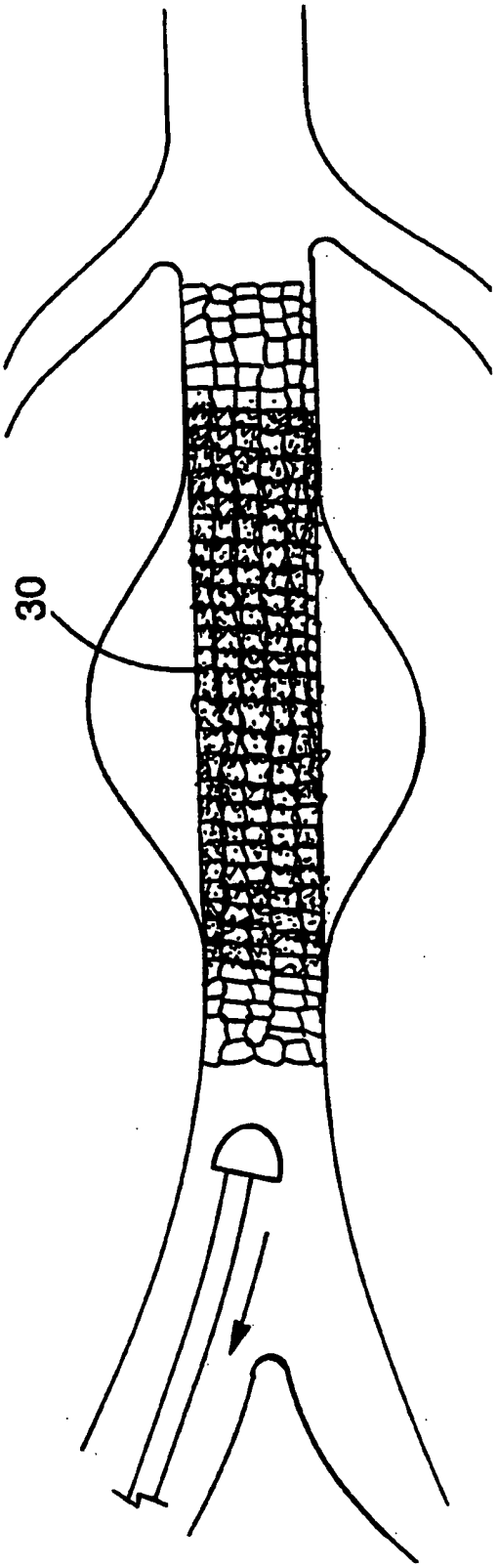


FIG. 7d

TUBULAR MEDICAL PROSTHESIS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Ser. No. 07/886,518, filed May 20, 1992, still pending, entitled "Device with a Prosthesis Implantable in the Body of a Patient", by Ernst Peter Strecker which is incorporated herein by reference.

FIELD OF THE INVENTION

This invention relates to tubular prostheses which are placed within the body.

BACKGROUND OF THE INVENTION

Tubular prostheses are used in body lumens to perform various functions. For example, a tubular stent may be used to maintain the opening of an esophagus that has been restricted by a tumor or a blood vessel restricted by plaque. Tubular grafts are used to substitute for or reinforce a weakened lumen, such as the aorta or other blood vessel that has been weakened by an aneurysm. In this latter technique, a graft of a knitted dacron may be used to advantage since the textured nature of the textile can induce blood clotting along the graft to contribute to the patency of the lumen formed by the graft.

Tubular prostheses for purposes such as the above may be positioned in the body lumen during a surgical procedure or may be delivered into the body by a catheter that supports the prosthesis in a compact form during percutaneous insertion and transport through body passageways to a desired site. Upon reaching the site, the prosthesis is expanded so that it engages the walls of the lumen. After this operation, the catheter is removed, leaving the device in the body.

The expansion technique may involve forcing the prosthesis to expand radially outwardly, for example, by inflation of a balloon carried by the catheter. Knitted, balloon expandable stents are discussed for example in Strecker U.S. Pat. No. 4,922,905, the entire content of which we hereby incorporate by reference. In another technique, the prosthesis is formed of an elastic material that can be arranged and held in a compact form for insertion and allowed to expand when in position by its own internal elastic restoring force. Knitted self-expanding stents are described in Strecker PCT EP 91/02194 and in Anderson U.S. Ser. No. 07/773,847, filed Oct. 9, 1991, the entire contents of both applications being incorporated herein by reference.

SUMMARY OF THE INVENTION

The invention provides prostheses with improved properties by forming the prostheses of multiple filaments or strands of different materials, one of which is a structural filament, preferably metal. In preferred embodiments, the strands are knit into a tubular form. In some embodiments, multiple strands of different materials are co-knit into a stent. The term "co-knit" as used herein refers to the knitting of multiple discrete strands in the knit pattern. In certain preferred embodiments, the strands are in a parallel co-knit form, by which is meant the strands of the various substances lie in parallel in all contiguous loops of the co-knit portion of the knit pattern. In other embodiments, the multiple strands of different materials are alternately knit such that adjacent rows of knit loops are of the different materials. In some embodiments, different regions of the prosthesis are formed of different sets of materials. In still further embodiments, a tubular structure of a first knit material is provided as a sheath over a second tubular structure of another knit material.

In one particular aspect, the invention features a tubular prosthesis having a tubular wall portion of loosely interlocked knitted loops constructed to function within a body lumen. The loops are formed of co-knitted strand materials where a first strand material of the loops is a metal wire that structurally defines the tubular shape of the prosthesis and maintains the shape when positioned in the lumen and a second strand material of the loops is co-knitted with the metallic strand and is formed of a predetermined substance selected to provide desired characteristics to the wall of the prosthesis.

In another particular aspect, the invention features a vascular graft prosthesis for bridging an aneurysm in an arterial lumen of the body. The graft has a tubular wall portion of loosely interlocked knitted loops constructed to function within the arterial lumen. The loops are formed of co-knitted strand materials where a first strand material of the loops is a metal wire that structurally defines the tubular shape of the prosthesis and maintains the shape when positioned in the lumen and a second strand material of the loops, co-knitted with the metallic strand, is formed of a predetermined non-metallic substance selected to provide desired characteristics to the wall of the prosthesis to enable it to perform its the function to effectively provide a patent covering over the structure of the graft.

In another particular aspect, the invention features a vascular prosthesis for use in an arterial lumen of the body. The prosthesis has a tubular wall portion of loosely interlocked knitted loops constructed to function within the arterial lumen. The loops are formed of parallel co-knitted strand materials where a first strand material of the loops is a metal wire that structurally defines the tubular shape of the prosthesis and maintains the shape when positioned in the lumen and a second strand material of the loops, co-knitted with the metallic strand, is a textured textile strand substance selected to enhance patency characteristics of the wall of the prosthesis.

In another particular aspect, the invention features a tubular prosthesis. The prosthesis has a tubular wall portion of loosely interlocked knitted loops constructed to function within a body lumen. The loops are formed of multiple strand materials where a first strand material of the loops is a metal wire that structurally defines the tubular shape of the prosthesis and maintains the shape when positioned in the lumen and a second strand material of knitted loops is formed of a predetermined substance selected to provide desired characteristics to the wall of the prosthesis.

In yet another particular aspect, the invention features a tubular prosthesis. The prosthesis has a tubular wall portion of a loosely interlocked regular pattern of strands constructed to function within a body lumen. The pattern is formed of multiple strand materials where a first strand material of the pattern is a metal wire that structurally defines the tubular shape of the prosthesis and maintains the shape when positioned in the lumen and a second strand material of the pattern, integrated with the metallic strand as part of the pattern, is formed of a predetermined substance selected to

provide desired characteristics to the wall of the prosthesis.

The features of the above aspects can be combined. In addition, various embodiments may include one or more of the following features. The prosthesis has an anchoring end portion of knitted loops which are knitted integrally with at least a portion of the co-knitted wall portion and formed of a strand material adapted to make contact with the wall of the body lumen to maintain the axial position of the prosthesis in the body lumen. The anchoring end portion is formed of contiguous loops of the first, metal strand material joined integrally with the wall portion that includes the co-knit second strand. The anchoring end portion of the prosthesis is self-expanding and is formed of elastic metal strand capable of being reduced in radial size without plastic deformation and retaining self-restoring capability such that the end portion can be reduced to a relatively small size for introduction lengthwise into the lumen, and when freed can radially self-expand to tubular form to engage the wall of the lumen. The anchoring end portion is formed of the plastically deformable metal and is knit integrally with the wall portion. The anchoring end portion is formed of metal strand flared to a diameter greater than the wall portion. The prosthesis has an anchoring portion at each of its axial ends. The wall portion is expandable to desired size by means of an internal expanding force or is self-expanding. The first strand material of the wall portion is a plastically deformable metal and the wall portion is expandable to a desired size by application of an internal expanding force. The first strand is selected from tantalum and nitinol. The second strand is selected from dacron, wool, nylon, polyethylene and teflon. The material of the second strand is textured to induce blood clotting. The prosthesis is sized for use as an aortic graft having, for example a porosity of about 4000 ml/min or more at implantation. The second strand is formed of a body fluid-dissolvable suture material. The second strand is an absorbing member that includes a drug. The second strand material is a metal, such as a dense metal that enhances the radiopacity of the prosthesis. The co-knit strands are in a parallel co-knit pattern. The first strand material and second strand material are continuously, single knitted to form regions of the tubular knit structure formed of the first material and regions of the knit structure formed of the second material. The first and second strand materials are alternately knitted to form successive alternating loop rows of the first and second material. The first and second strand materials are formed as separate knitted loop tubular structures and the second strand knitted loop structure extends coaxially with the first strand knitted loop structure and extends over an end of the first strand knitted loop structure to form a cuff to secure the first knitted structure to the second knitted structure. Rather than knitting, the tubular prosthesis pattern is formed by co-weaving or co-crocheting the strands, such as into a pattern formed of multiple parallel strands.

The invention also includes methods for manufacture and use of the prostheses described. Still other aspects of the invention will be understood from the following description and from the claims.

DESCRIPTION OF THE PREFERRED EMBODIMENT

We first briefly describe the drawings.

Drawings

FIG. **1** is a side view, in magnified scale, of an aortic graft prosthesis according to the invention using two different strand materials co-knit into a tubular structure in parallel co-knit fashion, while FIG. **1***a* is a greatly expanded view of adjacent loops in the wall portion of the graft of FIG. **1**;

FIG. **2** is a side view of another prosthesis according to the invention;

FIG. **3** is a side view of another prosthesis according to the invention, while FIG. **3***a* is an enlarged view of a portion of the prosthesis of FIG. **3**;

FIG. **4** is a side view of another prosthesis according to the invention;

FIG. **5** is a side view of another prosthesis according to the invention, while FIG. **5***a* is an end-on view along lines aa and FIG. **5***b* is a cross-sectional view along the lines bb, respectively in FIG. **5** and FIG. **5***c* is an enlarged view of a portion of the prosthesis of FIG. **5**.

FIG. **6** is a diagrammatic view of a circular knitting machine configured for alternate knitting while FIGS. **6***a*–**6***d* illustrate the operation of a needle used in a circular knitting machine and FIG. **6***e* illustrates a circular knitting machine configured for parallel co-knitting.

FIGS. **7**–**7***d* illustrate schematically, on a reduced scale, placement of an embodiment of an aortic graft prosthesis in the body.

DESCRIPTION

Referring to FIGS. **1** and **1***a*, an embodiment of a prosthesis according to the invention is a graft **10** which may be positioned in the abdominal aorta **38** within an aneurysm **40**. The graft **10**, of overall length L_1, e.g., about 8 cm, includes a wall portion **12**, of length L_2, e.g., about 5 cm, that spans the aneurysm **40** and anchoring end portions **14**, **14'** each of length L_3, e.g., about 1.5 cm, that engage healthy portions of the aorta to anchor the prosthesis in the lumen. As illustrated, the graft **10** is formed of loosely interlocked knitted loops of material. The diameter d_1 of the graft **10** and the respective lengths are variable, as discussed below, to accommodate various aorta diameters and aneursym conditions. For example, the diameters may be in the range of 10–20 mm and prosthesis lengths L_1 in the range of about 4–8 cm.

Referring particularly to FIG. **1***a*, in the wall portion **12**, the loops are formed by parallel co-knitting of a first strand material **16**, a metal, and a second strand material **18**, preferably of texturized filament or fiber. The first strand material substantially defines the tubular structure of the graft and is a selected metal strand of wire such as tantalum. The second strand material **18** is preferably non-metallic, e.g. a polymer or natural textile fiber or the like, such as a textile yarn, selected to provide a desired characteristic of the prosthesis to enable it to perform a desired function. In the case of an aortic graft, the second material is selected for its capability of inducing the clotting of blood. In these embodiments, the second strand material **18** is preferably a texturized material such as dacron yarn formed of crimped or texturized multiple monofilaments, typically in excess of about **20**, with multiple, randomly extending segments **22** that extend into the open area **25** between adjacent knitted loops.

The anchoring portions **14**, **14'** are formed of wire knitted strand **24**, that does not include a co-knit strand. Strand **24** is integral with the wall portion **12** and may be a knitted extension of the metal strand material **16**. (Alternately, the anchoring end portions may be a co-

knit structure which may be the same or different from the co-knit structure of the central wall portion.)

A particular aspect of this embodiment is parallel co-knitting to form rather loosely interlocked loops with selected, loop length, L_4, e.g. about 1.8 mm that provides substantial open area 25. This design facilitates wrapping the prosthesis into small size for delivery intralumenally. Wrapping produces a sliding action of adjacent loops within the open area that avoids stress concentrations in the wires, yet the size of the open area and texturized nature and number of strands formed of the second material provides strand components that extend within the open areas of the loops. By suitable selection, these components can be sufficient to produce clotting in a sufficiently short time that excessive bleeding through the graft will not occur when the graft is placed inside the lumen. A particular benefit of this design is that, generally, the graft need not be pre-clotted before placement. Over time in the body, the graft accepts cells, endothelializes and becomes a patent portion of the artery. The porosity of the graft may be, e.g., about 4000 ml/min or more at implantation. This degree of porosity facilitates migration of cells (e.g. fibroblasts and endothelial cells) into and through the knit structure such that cellular structure can be formed. (Graft porosity as measured by water filtration testing is discussed, for example, in Wesolowski, S. A. Dennis, C., *Fundamentals of Vascular Grafting*, New York, McGraw-Hill, 1963.)

Further, the loosely interlocked loops formed by the co-knitting process of metal wire and the other selected substance are free to slide with respect to each other while in use in the body. This ability for the loops to slide enhances the ability of the device to maintain its axial working length and resist migration when the prosthesis is locally radially compressed. Under such compression the loop structure may locally lengthen or shorten to accommodate similar changes in the vessel in which it is installed, as may occur for instance if the aorta is stretched. The loosely co-knitted structure also allows the graft to negotiate tortuous vasculature during delivery on a catheter because of its flexibility longitudinally.

The co-knitting has other advantages as well. For instance, it provides a mechanism for attachment of multiple strand materials without need for additional means such as tie strands and the like, although these optionally may be employed.

One embodiment of a graft as in FIG. 1 and 1*a* employs, in parallel with the metal strand, four parallel strands of dacron (44DTEX), each strand consisting of 27 filaments, full drawn R02 medical grade (available from E. I. DuPont de Nemours and Co., Wilmington, Del.). Before co-knitting, the strands are texturized by false twisting and set by radiation heating. Parallel co-knitting with a tantalum wire strand (0.10 mm) is carried out to produce a 10 mm diameter (d_1) graft with a circumferential loop count of 12 loops and a wall portion of 4 cm length (L_2) consisting of 29 co-knit rows and anchoring end portions, of 10 single knit rows of tantalum. The loop length of the knitted loops in the axial direction is about 1.8 mm.

Other Embodiments

Generally, the principle of combining different strands to form a prosthesis provides a ready ability to adapt the properties of the stent to suit various applications, the respective strands being selected to provide properties which enhance performance. In general, at least one of the strands will be selected for its structural properties to enable the stent to maintain an open passage. In many preferred embodiments such strands are of selected metal. The metal strand material may be of a metal selected to enhance radiographic visualization of the prosthesis during the delivery through a body lumen, the positioning at a desired site and the assessing of the efficacy of treatment. Particular advantages are achieved when the metal strand is formed of a highly radiopaque metal such as tantalum. The metal strand material also may be selected for features relating to its expandability, to enable a single size-prosthesis to be manufactured for use in lumens of somewhat varying size as may be encountered from patient to patient. The metal strand material may be a metal capable of yielding when the stent is expanded in the lumen by an internal radial force, such as by balloon expansion. Such a prosthesis is therefore size-selectable for the desired application. In other cases, the metal strand material is selected to form an elastically self-expanding prosthesis which may be reduced to a small diameter for introduction into the body and allowed to expand at a desired site by release of a restraint. Embodiments in this case would use an elastic metal strand such as nitinol wire, which also can enhance maintenance of the elasticity of the vessel in which it is placed and can be used to widen an occluded vessel. For example, the prosthesis may be used as a stent in the biliary duct or the esophagus to widen these ducts in the cases where they have been occluded by tumors. In the case of stents formed by co-knitting another strand with a self-expanding elastic metal, the co-knit portions may still require balloon expansion because of the restraining effect of the second strand, or to ensure good seating. The metal strand may also comprise a two component cored material as discussed in U.S. Ser. No. 07/861,253, filed Mar. 31, 1992, the entire contents of which are hereby incorporated by reference.

The second strand material may be a wool, nylon, polyester, polyethylene or teflon, selected e.g. for the degree of texture desired. Various embodiments may also include a strand adapted for drug delivery. The second strand material may also be a dissolvable suture material or an absorbent such as hollow absorbent material carrying drug that inhibits body rejection of the prosthesis or inhibits hyperplasia. The drug may be slowly releasable as the strand dissolves, finally leaving only the thin metal first strand to provide desired reinforcing structure through the loops of which healthy endothelial tissue can gradually grow without the chaffing or grinding effects that might occur at points of intersection of the strands that have dissolved. In other embodiments, both the first and second strands are metals that provide different desirable properties. For example, one strand may be an elastic material such as nitinol and the second strand a dense radiopaque strand such as tantalum that enhances the fluoroscopic visibility of the device. Preferably, in these latter embodiments, one or both of the metal strands include a polymer coating to avoid electrolytic corrosion induced by contact of dissimilar metals in an aqueous body fluid environment. The coating may be selected to be dissolvable. A drug may be incorporated in the coating so that, by the dissolving action, the drug is released over time. The rate of dissolution of a coating may be selected so that removal of the coating occurs at a desired time, to enable electrolytic corrosion to dissolve one of the

strands, thereby to reduce the amount of metal remaining in the body. The coating may also be seeded with fibrin on the surface to control a fibrin layer with the aim of forming neuro intima. A strand material employing a semipermeable membrane for drug delivery can also be used. One such material is described in EP 0441516, published Aug. 8, 1991, the entire contents of which is hereby incorporated by reference.

Different portions of a prosthesis can be tailored with specific, different properties, to achieve different functions, by using various strands of different materials at different locations, which are easily implemented during the knitting process. As illustrated above in FIGS. **1** and **1***a*, the anchoring portions **14**, **14'** can be, for example, axial knitted extensions of the metal strand material **16** which may be produced by ceasing co-knitting of the second strand material at a desired point in production. In some cases a second metal strand which can be of the same or different properties from the first metal can be added in this region to strengthen the anchoring portions or for other purposes.

In certain cases of an aortic graft, as discussed above with respect to FIGS. **1** and **1***a*, it is particularly advantageous not to have clot-producing strands in the anchoring region so that substantial clotting will not be induced at the end portions where it is not necessary and the mechanical properties of the metal strand can perform their function unimpeded to provide secure anchorage. The strands at the end portions may be selected to be elastic, self-expanding, or plastically deformable.

Alternatively, the metal strand at the anchoring ends may be a different strand material than either the first strand material or second strand material in the main body or wall portion of the stent, to produce a desired effect, such as self-expandability in the anchoring ends and balloon expandability in the wall portion. The anchoring end material can be co-knit to overlap with a portion of the wall portion.

Referring to FIG. **2**, a prosthesis **26** is illustrated having a wall portion **12** and anchoring ends **28**, **28'**. In this embodiment ends **28**, **28'** are flared outwardly to a diameter, d_2, such that they impress upon the inner wall of a body lumen for anchoring the prosthesis **26** in place. As with the embodiments above, the strands **25** at the anchoring ends may be selected to make the ends self-expanding or expanded by plastic deformation by an internal expansion device.

Referring to FIGS. **3** and **3***a*, in another embodiment, rather than parallel co-knitting, a stent **50** may be formed by continuous knitting a first strand material **52** and a second strand material **54** in an alternating, sequential co-knit fashion to form adjacent spiral patterns of loops along the length of the stent, resulting in successive alternating rows of different material in a single knit structure. In preferred embodiments, strand **52** is a metal strand, most preferably tantalum, and second strand **54** is a dissolvable, resorbable thread of material such as is used in dissolvable sutures. In a predetermined time, in the body, the thread strand **54** is dissolved leaving only circumferential rings of successive loops of metal which avoids strand intersections that could exert shearing forces or other damaging effects on surrounding and growing tissue. In preferred embodiments, drugs e.g., an antiproliferative, can be embedded in the dissolvable strand to gradually deliver the drug to surrounding tissue as the strand dissolves. In an alternative preferred embodiment, the first strand is a metal selected for its elastic properties and the second strand is a radiopaque metal, with one or both of the metals including a coating to inhibit, at least temporarily, the electrolytic degradation of the strands, as mentioned above.

Referring to FIG. **4**, in another embodiment, rather than parallel co-knitting, stent **60** is formed by continuous knitting of a first strand **62**, preferably a metal such as tantalum and a second strand **64** such as dacron in alternating regions, to perform specific functions. Metal strand **62** in the end regions provide anchoring portions while textile strand **64** provides a patent graft region.

Referring to FIGS. **5**–**5***c*, in another embodiment, rather than parallel co-knitting, a graft **70** is provided that is formed of a first, separately knitted tubular structure **72** formed of a first strand **73**, e.g. tantalum, and a second separately tubular knitted structure **74**, assembled coaxially within the first structure **72** and formed of a second strand **75**, e.g. dacron. At the ends **76**, **76'**, the second tubular knit structure **74** is rolled over the outside of the first knit structure to form a cuff, to secure the assembly together. The first and second tubular knit structures may also be secured by sewing them together. In an alternative construction, the second tubular knitted structure of dacron could be a continuously co-knitted extension of the first metal tubular structure and the dacron knitted structure is pulled through the center of the metal structure. In other embodiments, the fabric knitted structure is on the outside of the metal knitted structure or is sandwiched between two metal structures or the metal knitted structure is between two fabric knitted structures. In another embodiment two tubular members can be effectively formed as a double knit structure.

In the embodiments of the invention discussed in the above description, the prostheses are formed of knitted strands, in other embodiments, other methods of forming a tubular structure from strands such as co-weaving, co-crocheting and the like can also be used. In some cases, with knitted embodiments or otherwise, it may be desireable to use a velour which is a variant of knitted material in which loops of yarn extend outward from the surface of the fabric formed by the knit structure.

Manufacture

Tubular prostheses of the invention may be manufactured on a circular knitting apparatus. Referring to FIGS. **6**–**6***e*, knitting apparatus are diagrammatically shown. Referring to FIG. **6**, the apparatus includes a knitting head **92** for guiding a series of needles **94**, **94'** which are axially extended and retracted by a rotating (arrow **95**) contoured platen **96**. Spools **98**, **98'** feed strand material to the needles during the knitting operation. The knit structure **101** is produced around a plastic mandrel **100** which is drawn downward in the direction of arrow **102**.

Referring particularly to FIGS. **6***a*–**6***d*, the needles, such as needle **94**, include a needle head **106** and a pivoted needle tongue **108**. During the upstroke of the needle, the head **106** grasps a feed from the strand spool **98**, the tongue **108** being initially in the downward position (FIG. **6***a*). On the downstroke, the tongue **108** is deflected upward as it engages the portion of the knitting head **94**, thus enclosing the strand within the head (FIG. **6***b*). The downstroke continues for a selected length within the knitting head (FIG. **6***c*). On the upstroke, the strand deflects the tongue **108** downward,

thus releasing the strand from the needle head **106** (FIG. 6*d*). The cycle is repeated as the platen **96** rotates.

The contour of the platen is selected to drive the needles for forming a desired knit pattern. In the embodiment in FIG. **6**, needles **94**, **94'** disposed about the needle head **92** at 180° are synchronized to simultaneously pass through the stroke cycle by platen **96** which is contoured symmetrically with opposed raised sections **99**, **99'** and intervening valleys. By providing different strands on spools **98**, **98'**, the knit pattern will be a continuous alternating tubular knit structure **101** such as that described with respect to FIG. **3**, above.

For forming parallel co-knit structures, multiple strands are passed through each needle head to cause simultaneous parallel co-knitting. Referring to FIG. 6*e*, the circular knitting machine is shown configured for parallel co-knitting by providing strands from spools **110**, **110'**, **112**, **112'** so that needles **94**, **94'**are provided simultaneously with multiple strands of different materials. A platen **118** is provided which has a single raised section **120** to sequentially drive each needle about the periphery of the knitting head through the stroke cycle. The parallel co-knit structure **103** is formed on mandrel **100**. Co-knitting may be ceased by providing only a single strand to the needle heads, for example when knitting a graft such as in FIG. **1**, with a co-knit wall portion and integral single knit anchoring end portions.

Generally, the number of needles circumferentially disposed around the knitting head determines the number of circumferential knit loops. The size of the needle affects the narrowness of the loops; a smaller needle forms a narrower loop since the strand bends more acutely around the narrower needle head. The diameter of the knitting head affects the diameter of the knitted stent.

Delivery

The prostheses of the invention can be positioned by various means. For example, for a balloon expandable graft with balloon expandable anchoring end portions, the graft may be positioned using a catheter with a balloon having a length substantially the length of the graft and an inflated diameter sufficient to expand the graft to the desired maximum size and to smaller sizes by partial inflation. For a graft which has a self-expanding wall portion and self-expanding anchoring ends, the graft can be restrained to small size on a catheter with a constraint such as a sleeve which is removed to release the stent at the placement site. These self-expanding grafts may be wrapped around a distal portion of the catheter in a 'jelly roll' fashion.

Referring to FIGS. 7–7*d*, positioning of a graft having self-expanding anchoring ends and a balloon expandable wall portion is illustrated. The graft **80** is positioned at the distal end of a catheter **30** which includes an inflatable balloon **32** upon which the graft is placed and an axially slidable sleeve member **34** which is placed over the graft **80** to constrain the self-expanding anchoring ends **82**, **82'** and a balloon wall portion formed of a co-knit tubular structure including a clot-inducing strand and a metal strand. The catheter **30**, which for introduction through a vessel such as the iliac artery **36** has a diameter of about 20 French, is advanced to the aorta **38** that has been weakened by an aneurysm **40**. The catheter **30** positions the graft such that graft **80** spans the region effected by aneurysm **40** and axially therebeyond to portions **42**, **44** of the aorta that remain healthy but such that the graft will not interfere with the renal arteries **41**. In case of an approach through the femoral artery a smaller catheter (about 12 F) is used. In this latter case, the stent is constructed with a 5 to 1 ratio of expanded to compressed size. Placement of the graft should be accurate to within about +/−0.5 cm to properly position the anchoring ends **80**, **80'** which are typically about 1.5 cm in length on the healthy portions of the aorta.

Referring to FIG. 7*a*, the graft **80** is placed in the lumen by withdrawing the sleeve **34** axially (arrow **46**) which releases the restraint on end portion **82'** causing it to expand to engage the inner wall of the healthy portion **44** of the aorta.

Referring to FIG. 7*b*, with sleeve **34** completely removed from the prosthesis the anchoring end **82** similarly expands to engage the healthy portion **42** of the aorta, thus fixing the prosthesis in the lumen and positioning the wall portion **84**, which remains unexpanded, at the location of the aneurysm **40**.

Referring to FIG. 7*c*, a view in partial cross section, the balloon **32** is inflated to produce a radial force (arrow **48**) which expands the wall portion **84** to a desired diameter that approximates the diameter of the healthy portions of the aorta such that the wall portion of the graft does not engage the weakened tissue of the aneurysm.

Referring to FIG. 7*d*, after expansion of the wall portion **84**, the balloon **32** can be deflated and the catheter removed from the lumen, leaving the prosthesis **80** positioned across the aneurysm and securely anchored. As discussed above, clotting is induced by a non-metallic textured strand of the graft to fill the interstices between adjacent knitted loops within a reasonable time to form a patent covering over the wall portion of the graft.

Still other embodiments are within the following claims.

What is claimed is:

1. An implantable tubular prosthesis comprising:

a tubular wall portion of loosely interlocked knitted loops defining open areas in said tubular wall, said wall being formed of at least two separate strands of different materials that are parallel co-knitted to form a unitary wall structure including a first strand that is a metal wire that structurally defines the tubular shape of said prosthesis and maintains said shape when positioned in said lumen and

a second strand, parallel co-knitted with said first strand, and comprising a predetermined material selected to provide desired characteristics to the wall of said prosthesis.

2. The prosthesis of claim **1** wherein said second strand is formed of a body fluid-dissolvable suture material.

3. An implantable vascular graft prosthesis for bridging an aneurysm in an arterial lumen of the body, comprising:

a tubular wall portion of loosely interlocked knitted loops defining open areas in said tubular wall constructed to prevent excessive bleeding through the wall by inducing an initial clotting when the graft is placed in said lumen and to allow cells to migrate through said wall to endothelialize said graft,

said wall being formed of at least two separate strands of different materials that are parallel co-knitted to form a unitary wall structure including a first strand that is a metal wire that structurally defines

the tubular shape of said prosthesis and maintains said shape when positioned in said lumen and

a second strand, parallel co-knitted with said first strand, comprising a predetermined non-metallic material selected to extend at least partially into space defined by the knit loops of the first strand to induce said initial clotting while maintaining sufficient open area so cells can migrate through said wall to endothelialize the graft.

4. The prosthesis of claim 1 or 3 including an anchoring end portion of knitted loops, knitted integrally with at least a portion of said co-knitted wall portion and formed of a strand material adapted to make contact with the wall of said body lumen to maintain the axial position of said prosthesis in said body lumen.

5. The prosthesis of claim 4 wherein said anchoring end portion is formed of contiguous loops of said first, metal strand material joined integrally with the said wall portion that includes said co-knit second strand.

6. The prosthesis of claim 1 or 3 wherein an anchoring end portion of said prosthesis is self-expanding, being formed of elastic metal strand capable of being reduced in radial size without plastic deformation and retaining self-restoring capability, whereby said end portion can be reduced to a relatively small size for introduction lengthwise into said lumen, and when freed can radially self-expand to tubular form to engage the wall of said lumen.

7. The prosthesis of claim 6 wherein said wall portion is expandable to desired size by means of an internal expanding force.

8. The prosthesis of claim 1 or 3 wherein said wall portion is expandable to a desired size by means of an internal expanding force.

9. The prosthesis of claim 8 wherein said first strand material of said wall portion is a plastically deformable metal, said wall portion being expandable to a desired size by application of an internal expanding force.

10. This prosthesis of claim 9 having an anchoring end portion formed of said plastically deformable metal and is knit integrally with said wall portion.

11. The prosthesis of claim 1 or 3 having an anchoring end portion formed of metal strand flared to a diameter greater than the wall portion.

12. The prosthesis of claim 1 or 3 including an anchoring portion at each of its axial ends.

13. The prosthesis of claim 1 or 3 wherein said first strand is selected from the group consisting of tantalum and nitinol.

14. The prosthesis of claim 13 wherein said second strand is selected from the group consisting of dacron, wool, nylon, polyethylene and teflon.

15. The prosthesis of claim 1 or 3 wherein the material of said second strand is textured to induce blood clotting.

16. The prosthesis of claim 15 wherein said prosthesis is sized for use as an aortic graft.

17. The prosthesis of claim 15 wherein said graft has a porosity of about 4000 ml/min or more at implantation.

18. The prosthesis of claim 1 or 3 wherein said wall portion includes a highly elastic strand and is self-expanding.

19. The prosthesis of claim 1 or 3 wherein said second strand is an absorbing member that includes a drug.

20. The prosthesis of claim 1 or 3 wherein said co-knit strands are in a parallel co-knit pattern.

21. An implantable vascular prosthesis for use in an arterial lumen of the body comprising:

a tubular wall portion of loosely interlocked knitted loops defining open areas in said tubular wall, said wall being formed of at least two separate strands of different materials that are parallel co-knitted to form a unitary wall structure, including a first strand of said loops that is a metal wire that structurally defines the tubular shape of said prosthesis and maintains said shape when positioned in said lumen and

a second strand, parallel co-knitted with said first strand and comprising a textured textile strand selected to provide enhanced clot-inducing characteristics to the wall of said prosthesis.

22. The prosthesis of claim 21 wherein said wall portion is expandable to a desired size by means of an internal expanding force.

23. The prosthesis of claim 22 wherein said first strand material of said wall portion is a plastically deformable metal, said wall portion being expandable to a desired size by application of an internal expanding force.

24. The prosthesis of claim 23 having an anchoring end portion formed of said plastically deformable metal and knit integrally with said wall portion.

25. An implantable tubular graft prosthesis comprising:

a tubular wall portion of a loosely interlocked regular pattern of strands defining open areas in said wall constructed to prevent excessive bleeding through the wall by inducing an initial clotting when the graft is placed in said lumen and to allow cells to migrate through said wall to endothelialize said graft,

said wall being formed of at least two separate strands of different materials that are integrated in parallel in said pattern to form a unitary wall structure, including a first strand that is a metal wire that structurally defines the tubular shape of said prosthesis and maintains said shape when positioned in said lumen, and

a second strand, in parallel extension and integrated with said first strand as part of said pattern forming said wall, said second strand formed of a material selected to extend at least partially into space defined by the first strand to induce said initial clotting while maintaining sufficient open area so said cells can migrate through said wall to endothelialize said graft.

26. The tubular prosthesis of claim 25 wherein said pattern is formed by co-weaving said strands.

27. The tubular prosthesis of claim 25 wherein said pattern is formed by co-crocheting said strands.

28. The tubular prosthesis of claim 26 or 27 wherein said pattern is formed of multiple parallel strands.

29. The prosthesis of any one of claims 1, 3 wherein said second strand material comprises a multi-filament textile which has been texturized to produce segments that extend radially outward from said strand.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,366,504

DATED : November 22, 1994

INVENTOR(S) : Erik Andersen et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Cover page, under [56] References Cited, FOREIGN PATENT DOCUMENTS, after patent number 1173811 delete "12/1969", insert --2/1969--.

Col. 9, line 51, "roll°" should be --roll'--.

Col. 12, claim 29, line 61, "1, 3" should be --1 or 3--.

Signed and Sealed this

Ninth Day of April, 1996

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks